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8-0900-9110-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Adoption of Permanent Rules of the State Department of Health Relating to Licensing, Administration, and Health Services in Licensed Nursing Homes

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Jon L. Lunde at 9 a.m. on November 21, 1994, at the Capitol View Conference Center, 70 West County Road B-2, in Little Canada, Minnesota. The hearing was held pursuant to an Order for Hearing dated September 13, 1994.

Approximately 31 persons attended the hearing. Mary Stanislav, Assistant Attorney General, 520 Lafayette Road, Suite 200, St. Paul, Minnesota 55155-4199, appeared on behalf of the Department. The Department's hearing panel consisted of H. Michael Tripple, Assistant Director of the Facility and Provider Compliance Division and Rule Writers, Dena Dunckle and Maggie Friend. The hearing continued until all interested persons, groups and associations had an opportunity to be heard concerning the adoption of the rules proposed by the Department in this proceeding.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. §§ 14.131 to 14.20 to hear public comments and determine if the Minnesota Department of Health (Department) has fulfilled all relevant, substantive and procedural requirements of law applicable to the adoption of rules, if the proposed rules are needed and reasonable, and if any modifications to the rules proposed by the Department after initial publication in the State Register are impermissible, substantial changes.

The record remained opened for the submission of written comments for 20 calendar days following the hearing--to December 12, 1994. Pursuant to Minn. Stat. § 14.15, subd. 1, five working days were allowed for the filing of responsive comments. At the close of business on December 19, 1994, the rulemaking record closed for all purposes. Approximately 65 written comments were filed by interested persons during the comment period. The Department also submitted written comments responding to matters discussed at the hearing and in written comments. The due date for completion of this Report was extended to February 16, 1995 by the Chief Administrative Law Judge under Minn. Stat. § 14.15, subd. 2 (1994).

This Report must be available for review to all affected individuals upon request for at least five working days before the agency takes any further action on the rule(s). The agency may then adopt a final rule or modify or withdraw its proposed rule. If the Department makes changes in the rule other than those recommended in this report, it must submit the rule with the complete hearing record to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of a final rule, the agency must submit it to the Revisor of Statutes for a review of the form of the rule. The agency must also give notice to all persons who requested to be informed when the rule is adopted and filed with the Secretary of State.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On September 15 1994, the Department filed the following documents with the Chief Administrative Law Judge:

(a) A copy of the proposed rules. A copy of the rules certified by the Revisor of Statutes wasn't filed until October 18, 1994.
(b) The Order for Hearing.
(c) The Notice of Hearing proposed to be issued.
(d) A Statement of the number of persons expected to attend the hearing and the estimated length of the Agency's presentation.
(e) The Statement of Need and Reasonableness (SNR).
(f) A Statement of Additional Notice.

2. On October 17, 1994, a Notice of Hearing and a copy of the proposed rules were published at 19 State Register 785-819. Ex. 10.

3. On October 12, 1994, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving such notice. Exs. 5 and 6.

4. On October 12, 1994, the Department's SNR was mailed to the Legislative Commission to Review Administrative Rules (LCRAR) for purposes of complying with Minn. Stat. §§ 14.131 and 14.23 (1992). Ex. 7.

5. On October 18, 1994, the Department filed the following documents with the Administrative Law Judge:

(a) The Notice of Hearing as mailed.
(b) The Agency's certification that its mailing list was accurate and complete at the time the hearing notice was mailed.
(c) An affidavit of mailing stating that the Notice was mailed to all persons on the Agency's list.
(d) An affidavit of additional notice. Ex. 8.
(e) A copy of the State Register containing the proposed rules.
(f) All materials received following a Notice of Intent to Solicit Outside Opinion published at 16 State Register 1230 on November 18, 1991 and a copy of the notice.
(g) An affidavit of mailing stating that the SNR was mailed to the Legislative Commission to Review Administrative Rules.

The Department didn't provide the names of the persons who would represent it at the hearing or the names of any other persons solicited to appear on its behalf. The filed documents were available for inspection at the Office of Administrative Hearings from the date of filing to the date of the hearing.

6. The initial period for the submission of written comments and statements remained open through December 12, 1994, the usual, five-working-day period having been extended by Order of the Administrative Law Judge to 20 calendar days following the hearing. The record closed on December 19, 1994, the fifth business day following the and of the initial comment period.

7. The Department didn't file any written comments during the initial comment period which ended on December 12, 1994. All comments were filed at the end of the second comment period. Under Minn. Stat. § 14.15, subd. 1, most of the Department's comments were due at the close of the initial comment period. The statute contemplates that the Department and the public will file their initial comments at the close of the initial comment period so each of them can comment on the other's initial submissions during the second comment period. When no departmental comments are filed until the end of the second comment period, the public has no opportunity to comment on the Department's submission. This is contrary to the purposes of the statute. Nonetheless, the Department's failure to file any comments at the end of the first comment period was a harmless error for purposes of Minn. Stat. § 14.15, subd. 5. It didn't deprive anyone of an opportunity for meaningful participation because nobody asked to review the Department's comments at any time between December 12 and December 19. Hence, if the Department had filed its comments earlier no one would have reviewed and commented on them.

8. The Department's SNR was issued on September 13, 1994--the same day the Commissioner issued her Order for Hearing. Under Minn. Stat. § 14.131, the SNR should have been mailed to the LCRAR the same day. It wasn't mailed until October 12, 1994. However, the delay had no effect on any person's opportunity to participate meaningfully in this proceeding. Therefore, the delay was harmless for purposes of Minn. Stat. § 14.15, subd. 5.

Statutory Authority

9. For the most part, when determining whether the agency has statutory authority to adopt rules, the main focus is on the agency's general rulemaking authority. Its authority to adopt each particular provision generally isn't considered unless public comments clearly identify and describe a legal issue and legal arguments and authorities are cited which are sufficient to decide the legal issues raised.

In its Notice of Hearing the Department cited Minn. Stat. §§ 144A.04, subd. 3 and 144A.08 and Minn. Laws 1991, c.292, art. 4, § 55 as its statutory authority for the rules proposed in this proceeding. Section 144A.08 gives the Commissioner of Health (Commissioner) broad rulemaking authority. It states:

> Subdivision 1. Establishment. The commissioner of health by rule shall establish minimum standards for the construction, maintenance, equipping, and operation of nursing homes. The rules shall to the extent possible assure the health, treatment, comfort, safety and well being of nursing home residents.

Section 144A.04, subd. 3 requires that nursing facilities comply with any rules promulgated by the Commissioner but does not, by itself, authorize the promulgation of rules. Nonetheless, the rulemaking authority in section 144A.08, subd. 1 authorizes the rules proposed in this proceeding.

Violations of the rules proposed in this proceeding can result in the assessment of monetary penalties. The Department has authority to assess penalties for violations of these rules under Minn. Stat. § 144A.10 (1994). Most of the proposed penalties are the same as those which can now be imposed for violations of current rules which are being reenacted in this proceeding. The penalty provisions received little public attention and were shown to be necessary and reasonable.

10. Minn. Laws 1991, c. 292, art. 4 § 75--erroneously referred to as § 55 in the SNR--also doesn't contain a grant of rulemaking authority. However, it mandated the study which resulted in the rule changes in this proceeding. Section 75 states:

> The commissioner of health shall study the regulation of long-term care facilities and report to the legislature by January 15, 1992, with any recommendations for changes in the current regulatory structure. The study must address at least the following issues:
>
> (1) the possibility of unifying the federal state enforcement systems;
> (2) the effectiveness of existing enforcement tools;
> (3) the appropriateness of current licensure standards; and
> (4) alternative mechanisms for dispute resolution.

The required study, commonly known as the "Nursing Home Regulatory Reform Project" involved a review of all current rules relating to nursing homes and boarding care homes.

Rule Development

11. The goal of the Nursing Home Regulatory Reform Project

> . . . is the development of a comprehensive regulatory system that provides an appropriate level of protection to resident health and safety, provides a clear statement of provider responsibility, and promotes an effective regulatory process. The analysis necessary to achieve this goal identifies those state law and rule provisions, not currently part of the federal enforcement regulations, that need to be retained. Provisions remaining in state law and rule after this analysis and revision would complement the federal enforcement provisions. They would build on the strengths in the federal regulatory system, while retaining those provisions of state regulations that are deemed essential to the maintenance of the high standards of care found in Minnesota. The outcome would be the elimination of state regulations that are not needed, even some for which there are no corresponding federal provisions. The proposed changes would result in the integration of the state and federal survey processes to a far greater extent than is presently possible.

SNR at 3.

The proposed rules are designed to address new federal requirements,[1] changes in the practice and provision of long-term care services, and findings made during the Department's study. They replace or amend rules in Minn. Rules Chapters 4655 and 4660. The rules relate to licensing, administration and operation, restraints, resident assessments, resident care plans, clinical records, nursing services, medical directors, medical services, dental services, infection control, medication and pharmacy services, penalties, and technical matters.

12. In the development of the rules proposed in this proceeding, the Department obtained input from all interested persons and groups. It consulted with legislators, residents and their families, professional organizations, other state and federal officials, and national experts. In addition, it surveyed Resident Councils and Family Councils to obtain information regarding resident rights, needs, safety, and other issues. In 1991, the Commissioner also appointed a 15-member Steering Committee to provide policy direction to the Department in the regulatory reform process. It also established 15 workgroups to deal with specialized areas such as medical records and nursing services. The workgroups were directed to review needed documentation, consider methods of incorporating outcomes into the regulatory system, and address resident interests.

Standard of Reasonableness

13. In reviewing the rules, the Administrative Law Judge must decide if they are necessary and reasonable. Reasonable rules must have a rational basis. The Minnesota Court of Appeals has held that a rule is reasonable if it is rationally related to the end sought to be achieved by the statute. Broen Memorial Home v. Minnesota Department of Human Services, 364 N.W.2d 436, 440 (Minn. Ct. App. 1985); Blocker Outdoor Advertising Company v. Minnesota Department of Transportation, 347 N.W.2d 88, 91 (Minn. Ct. App. 1984). In Manufactured Housing Institute v. Pettersen, 347 N.W.2d 238, 244 (Minn. 1984) the Minnesota Supreme Court held that an agency must "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken." All that is required is that agency rules be the product of reasoned thought and based on a consideration of relevant factors. The agency is not required to adopt the most reasonable rule. It is authorized to select any reasonable alternative.

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1. The federal Nursing Home Reform Act was part of the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203). It is often referred to as "OBRA 87."

Many of the rules proposed in this proceeding already exist and are merely being reenacted. Under Minn. Rules, pt. 1400.0500, subp. 1C. (1993), the Department is not required to establish the need and reasonableness of existing rules. That includes rules that are merely being reenacted and those which are being reenacted without any significant substantial language changes.

This Report does not specifically address the need and reasonableness of each rule or the Department's statutory authority for each rule. All comments were considered even if not addressed herein. Any rules not specifically addressed were shown to be authorized, necessary and reasonable. Furthermore, unless specifically noted to the contrary herein, none of the rule changes prepared by the Department after the rules were initially published involve substantial change for purposes of Minn. Stat. § 14.15, subd. 3 and Minn. Rules, pt. 1400.1100 (1993).

Most of the rules repeat or elaborate on current rules and are consistent with applicable statutes and federal regulations and guidelines. For the most part, the rules were favorably received and the Department diligently, thoroughly and reasonably considered public comments.

14. Several persons commented on the Department's use of the word "must" rather than "shall", and questioned rules which incorporate other publications by reference. The must-shall issue is not addressed. Under Minn. Stat. § 14.07, subd. 1(a) (1994), the decision to use "must" rather than "shall" is governed by guidelines published by the Revisor of Statutes. The Department followed those guidelines here as required by the statute. Similarly, the decision allowing the Department to incorporate other materials by reference is one the Revisor makes under Minn. Stat. § 14.07, subd. 4. Only the need and reasonableness of incorporated material is subject to review in this proceeding. The Department established the need and reasonableness of the material it proposes to incorporate by reference in these rules.

LICENSING

15. 4658.0010. Definitions.

Part 4658.0010 contains definitions of key words used in the proposed rules. For the most part, the ten definitions initially proposed are based on current definitions in Part 4655.0100, subps. 1 and 2 (1993). The need and reasonableness of reenacting current rules generally need not be established by an agency in a rulemaking proceeding. Minn. Rules, pt. 1400.0500, subp. 1C (1993). Nonetheless, comments relating to new and existing definitions are considered herein.

16. Subp. 2. Convalescent and nursing care (C&NC) unit. This rule defines the words "convalescent and nursing care (C&NC) unit." The definition is nearly identical to the current definition in Part 4655.0100, subp. 4 (1993). David E. Holmstrom, Executive Director of the Minnesota Board of Pharmacy (Ex. 53) questioned whether the words defined in this rule are still in use. In its response, the Department indicated

that a number of facilities use the term and that its necessary to specify that the licensing rules apply to these units. Also, the term is used in the rules. For example, Part 4658.0040, subp. 3B relates to a hospital administrator's authority to serve as a C&NC's administrator. The rule proposed is necessary and reasonable.

17. Subp. 5. Licensed nurse. This rule defines the term "licensed nurse." Its identical to the current definition in Part 4655.0100, subp. 6 (1993), which defines a licensed nurse as "a registered nurse or a licensed practical nurse." As suggested by Joyce M. Schowalter, Executive Director of the Minnesota Board of Nursing (Ex. 73) the Department proposes to define the word "nurse" rather than the term "licensed nurse", because all persons using the title of nurse must be licensed, and to reference the statutes governing a nurse's licensure and practice. The definition will read as follows:

> "Nurse" means a registered nurse or a licensed practical nurse licensed by the Minnesota Board of Nursing or exempt from licensure in accordance with Minnesota Statutes sections 148.171 to 148.285.

The definition proposed by the Department is slightly different than that proposed by Ms. Schowalter because the Department added the words "or exempt from licensure." Also, the new definition does not accomplish Ms. Schowalter's desire to clarify a nurse's practice. Therefore the Department should consider amending the new definition further to read as follows:

> "Nurse" means a registered nurse or a licensed practical nurse licensed by the Minnesota Board of Nursing, or exempt from licensure, and practicing in accordance with Minnesota Statutes sections 148.171 to 148.285.

This change would clarify the statutes which under which nurses are licensed and practicing. If adopted, the further amendment would not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

18. Subp. 7. Nursing assistant. This rule defines a "nursing assistant" as:

> . . . A nursing home employee who is assigned by the director of nursing services to provide or assist in the provision of nursing or nursing-related services under the supervision of a registered nurse. Nursing assistant includes nursing assistants employed by nursing pool companies but does not include a licensed health professional.

Darrell R. Shreve, commenting on behalf of the Minnesota Association of Homes for the Aging (MAHA), suggested that the definition be amended by adding language specifically excluding nurses. Patti Cullen, commenting on behalf of Care Providers of Minnesota (CPM), suggested that the definition be amended to recognize that licensed practical nurses, and not just registered nurses, supervise the day-to-day activities of nursing assistants. Exs. 22 and 47.

The definition proposed by the Department is consistent with the definition of "nursing assistants" in Minn. Stat. § 144A.61, subd. 2 and is, therefore, necessary and reasonable. Although licensed practical nurses may be involved in the day-to-day supervision of nursing assistants, the definition need not recognize the propriety or extent of a licensed practical nurse's supervisory authority over nursing assistants. To the extent those practices are authorized, the rule, like the statute, properly places general supervisory responsibility on registered nurses.

19. Subp. 8. Nursing home. This rule defines the term "nursing home" as a facility or unit used to provide care to aged or infirm persons needing nursing care and services. It goes on to list some examples of nursing care. Jenean M. Erickson, president of Yorkshire Manor Nursing Facility, suggested that the term "nursing home" be replaced with the term "nursing facility" because the latter is used in federal statutes. Ex. 27. The Minnesota Nurses Association and the Board of Nursing had more detailed comments. Exs. 68, 73. They suggested that nursing care and the types of residents served should be described with more particularity. The Board of Nursing also suggested that the definition of nursing care should based on the scope of nursing practice as set forth in the Nurse Practice Act.

In response to these comments, the Department has decided to adopt the definition of "nursing homes" contained in Minn. Stat. § 144A.01, subd. 5 and to adopt a separate definition of "nursing care" using the definition in Minn. Stat. § 144A.01, subd. 6 (1994). The rule, as amended, is necessary and reasonable. An agency need not elaborate on statutory definitions, and the Department's decision to use the term "nursing home" rather than "nursing facility" is consistent with the words used in governing statutes. Hence, the rule, as amended, is necessary and reasonable. Furthermore, the amendments made to the definition originally proposed are not substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993), because the statutory definitions have always applied and merely adopting them by reference does not change the law in effect when the rules were proposed.

Sometimes statutory definitions are incomplete or ambiguous. In such cases, agencies are encouraged to elaborate on them. There is no indication in the record, however, that reliance on the statutory definitions mentioned is inappropriate, fails to address ambiguities or is inappropriate on some other ground.

20. Subps. 12, 13, and 14. In response to a suggestion made by the Board of Nursing, the Department proposes to adopt definitions of the terms "nurse practitioner", "physician", and "physician designee". The new definitions are as follows:

> Subp. 12. Nurse practitioner. "Nurse practitioner" means a registered nurse who has graduated from a program of study designed to prepare a registered nurse for advanced practice as a nurse practitioner and who is certified through a national professional nursing organization listed in the Board of Nursing rules.
>
> Subp. 13. Physician. "Physician" means a person licensed by the Minnesota Board of Medical Practice or exempt from licensure in accordance with Minnesota Statutes Chapter 147.

Subp. 14. Physician designee. "Physician Designee" means a nurse practitioner or physician assistant who has been authorized in writing by the physician to perform medical functions.

The three additional definitions proposed by the Department clarify words used in the proposed rules and are necessary and reasonable. The definitions do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993). However, the Department should also consider amending the definition of the word "physician" consistent with recommendation made for the word "nurse."

21. Subp. 15. Time periods. This rule contains material proposed after the hearing. In response to many comments, the Department has decided that nursing homes should have more flexibility in performing required acts under the rules. To give them more flexibility, it has replaced provisions requiring action at a specific time (e.g., every 30 days) with rules requiring action weekly or monthly, for example. It has also proposed definitions of the various time periods which give nursing homes flexibility in the timing of required action. The new rule defines the term "time periods" as follows:

Time periods means the minimum and maximum times allowed to complete an activity. Time periods are defined as:

A. For purposes of this rule "weekly" means a time period which requires an activity to be completed at least 52 times a year within intervals ranging from six to eight days.

B. For purposes of this rule "monthly" means a time period which requires an activity to be completed at least 12 times a year within intervals ranging from 27 to 33 days.

C. For purposes of this rule "quarterly" means a time period which requires an activity to be performed at least 4 times a year within intervals ranging from 81 to 89 days [sic].

The cited definitions were adopted in response to comments that the Department should not be prescriptive in requiring that something be performed on a specific day because it might result in scheduling problems. Care Providers of Minnesota suggested, for example, that the rule should define monthly as "no less than 20 days or greater than 40 days"; that weekly be defined as "no less than 5 days or greater than 10 days"; and that quarterly be defined as a period time no less than 75 days or greater than 105 days." Ex. 47. Rosemary Jellen, R.N., stated that she could not think of any occasions where documentation required on a weekly basis and performed on the sixth or eighth day instead of the seventh impacted resident care. Ex. 49.

The Department's decision to use the terms "weekly", "monthly", and "quarterly" rather than using specific time periods such as "7 days", "every 30 days", and "90 days" is necessary and reasonable and the new rule, defining the meaning of the terms "weekly", "monthly", and "quarterly" does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993). It is desirable to give facilities some flexibility in meeting deadlines when resident care and safety does not require that something be done on a particular day. The rule language proposed by the Department (Ex.

82, at 3) contains a typographical error, however. Under the rules, "quarterly" was intended to mean an activity which must be performed at least four times annually within intervals ranging from 81 to 99 days and not from 81 to 89 days. Also, the Department should consider inserting the words "for purposes of Chapter 4658," at the beginning of the second sentence of the new definition and eliminating the words "for purposes of this rule" under items A, B, and C.

22. The Board of Nursing suggested that the Department also adopt definitions of the terms "authorized prescriber", "legal representative", "comprehensive resident assessment", and "comprehensive plan of care." The Department concluded that additional definitions are unnecessary. It noted that terms "authorized prescriber" and "legal representative" are adequately addressed by statute. Further, the Department chose not to define "comprehensive resident assessment" and "comprehensive plan of care" on the grounds that those terms are used in federal certification regulations and are commonly used and understood by nursing home staff. In the Department's view, Minn. Rules, pts. 4658.0400 and 4658.0405 adequately describe what must be included in the comprehensive resident assessment and comprehensive plan of care. The Department's decisions regarding the additional definitions proposed were shown to be necessary and reasonable.

Part 4658.0015. Licensing In General.

23. Part 4658.0020 contains general licensing requirements. The rules require the licensure of nursing homes, set annual fees for licensure, require license posting, and generally require separate licenses for facilities located on different premises. The language in this part was not the subject of any public comment and was shown to be necessary and reasonable. Nonetheless, the Department should consider two issues. First, under subpart 2, it is not clear whether a full year's fee is required when the number of licensed beds in a nursing home is increased during the term of a license. If a full year's fee is required, the Department should consider adding the words "full year's" immediately before the word "fee" on page 10, line 10 of the proposed rule. Also, the Department could consider clarifying the circumstances when separate licenses are required. The words "maintained on separate premises" are somewhat ambiguous. For example, it is not clear if a nursing home consisting of two separate but connected buildings must have two licenses. It is suggested, therefore, that clarification be considered before the rules are finally adopted.

4658.0025. Procedures For Licensing Nursing Homes.

24. This part contains the procedures for licensing nursing homes. Subparts 1 through 13 of this part contain language nearly identical to that in current rules--Part 4655.0320. The rule received little public comment and was shown to necessary and reasonable. Nonetheless, those subparts subject to public comment and which merit further consideration are discussed below.

25. Subp. 15. Disclosure of controlling persons. This rule, citing Minn. Stat. § 144A.03, states that "the nursing home licensing application must identify the name and address of controlling persons of the nursing home. . . ." Subpart 15 is a revision of current rule 4655.0320, subp. 15.

Although Care Providers of Minnesota suggested that this section is unnecessary, the Department may duplicate statutory requirements in its rules. Furthermore, the Department is not required to establish the need for this rule because it replaces a rule containing substantially identical language.

26. Subp. 16. Disclosure of managerial employees. This rule requires nursing homes to provide the name and address of all administrators, assistant administrators, directors of nursing, medical directors, and service directors, and "indicate their previous work experience in nursing homes during the past two years." The current rule--Minn. Rules, pt. 4655.0320, subp. 16--only requires the names and addresses of assistant administrators and service directors and their previous work experience in Minnesota nursing homes during the past two-year period. Care Providers of Minnesota objected to the expanded language in the new rule. In its view, the Department failed to establish the rule's need and reasonableness. Furthermore, it argued that the words "service directors" are undefined and uncertain. Because of continuing staff changes, CPM is concerned that nursing homes will be required to update information provided to the Department on a regular basis for no particular reason.

The Department proposes to clarify the persons covered by the rule by replacing the words "service directors" (page 16, line 22) with the words "directors of nursing home services." The new language proposed does little to clarify the scope of the rule. The words "service directors" and "directors of nursing home services" are ambiguous. Furthermore, the rule does not indicate when the managerial employees' identities must be disclosed. This should be clarified. Under Minn. Stat. § 14.02, subd. 4, rules must be designed to make the law "specific". The Department has an obligation to adopt rules that are reasonably understandable under Minn. Stat. § 14.05, subd. 1. The Department should consider using language like that used in subp. 15 to clarify when a nursing home must disclose its managerial employees. Subpart 15 says the information must be on the license application.

Although CPM stated that the Department failed to establish the rule's need and reasonableness, such a showing generally need not be made when a new rule repeats the language of an existing rule. Currently, under Minn. Rules, pt. 4655.0320, subp. 15 and 16, nursing homes must report the identity of their administrators, assistant administrators, and service directors. Under the new rule, the directors of nursing and medical directors must also be disclosed. Including the latter two in the rule, does not expand current language because both those persons apparently are "service directors." However, the other "directors of nursing services" are not so certain. Therefore, it is recommended that the Department eliminate the words "directors of nursing home services" and specify the particular services which are covered. It's not clear if persons responsible for resident activities, pharmacy services, laundry, housekeeping, and meals must be reported.

Part 4658.0040. Variance and waiver.

27. Part 4658.0040 implements the Commissioner's authority under Minn. Stat. § 144A.04 to grant waivers from strict compliance with Departmental rules. Charles T. Thompson, Administrator of North Ridge Care Center, suggested that the rule contain a time limit within which the Commissioner

will grant, revoke, deny, or refuse to renew a waiver under subparts 3 and 6. Ex. 19. The Department rejected his suggestion because the complexity of waiver issues may vary greatly. The Administrative Law Judge is persuaded that the absence of time limitations does not affect the need and reasonableness of the rule. The Commissioner is not required to set time limits for dealing with issues of variable complexity and importance. The rule, as proposed, which is a compilation of current Parts 4655.1000 through 4655.1060, was shown to be necessary and reasonable.

ADMINISTRATION AND OPERATION.

Part 4658.0050. Licensee.

28. Subpart 1. General duties. This rule is a revision and expansion of current Part 4655.1200, subp. 1. It makes the licensee responsible for the management, control and operation of a nursing home, and requires that the nursing home be

> . . . managed, controlled, and operated in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

The cited language, taken from the second sentence of the rule, is identical with the language in 42 C.F.R. § 483.75 (1994).

Several persons commented on subpart 1. MAHA recommended deletion of the second sentence on the ground that it merely reiterates the first. Ex. 82. Jenean Erickson suggested adding language to the second sentence which would require the effective and efficient use of resources to "provide care and services to residents" so that they may attain the highest level of well being possible. Ex. 27. Steven Chies of North Cities Health Care, Inc., suggested that the words "effective and efficient" be clarified further. Ex. 75. The Administrative Law Judge is not persuaded that the second sentence is redundant or that further clarification is required. When a rule is more than a general policy statement and when a violation can result in the imposition of penalties, the rule must be reasonably clear. Violations of Part 4658.0050, subp. 1 can result in the imposition of a $250 penalty under Part 4658.0190A. Nonetheless, because the second sentence of the rule reiterates federal regulatory language and applies to a broad range of activities, the Administrative Law Judge is persuaded that it is necessary, reasonable and sufficiently clear. An agency is not required to adopt precise rules when doing so is not feasible and case-by-case determinations must be made. Can Mfrs. Institute, Inc. v. State, 289 N.W.2d 416.423 (Minn. 1979). Proper application of the rule can be developed case-by-case based on the unique facts involved.

29. Subp. 2. Specific duties. This rule requires the licensee to "develop written by-laws or policies which are available to all members of the governing body and assume legal responsibility for matters under its control, for the quality of care rendered and for compliance with applicable laws and rules of legally authorized agencies." The language of the rule is identical to current Part 4655.1200, subp. 2. Therefore, its need and reasonableness need not be established in this proceeding.

Susan Stout and Dianne Hansen, commenting on behalf of the Minnesota Nurse's Association, suggested that the Nurse Practice Act should be referred to as the one of the applicable laws nursing home licensees must follow. Ex. 68. The Department rejected that suggestion. The Department is not required to refer to the Nurse Practice Act because it is only one of many laws nursing homes must abide by under the rules.

Although the Department may adopt subpart 2 as written, it should consider two changes. First, it should consider further clarifying the types of by-laws or policies it has in mind. Otherwise, a nursing home might have by-laws and policies covering some matters, but not others having even greater importance to the well being of residents. Also, instead of requiring compliance with "applicable" laws and rules, the Department should consider requiring compliance with laws and rules relating to the health, safety and sanitation of facilities or which otherwise bear directly on the welfare and care of nursing home residents. It is questionable, for example, whether the Department can require nursing home to comply with tax laws or punish any tax violations which occur.

30. Subp. 3. Responsibilities. Subpart 3A requires each nursing home licensee to disclose the persons having an interest of 10 percent or more in the nursing home and report any changes within 14 days of their occurrence. The rule goes on to require reporting of the ownership of the relevant corporation, partnership, lessee, or franchisee. Subpart 3A repeats the requirements currently found in Part 4655.1200, subp. 2A and its need and reasonableness need not be established. The only change in the existing rule proposed by the Department is that disclosure of the persons having an interest in the home's ownership must be reported "within 14 days" rather than "promptly."

Patti Cullen, of CPM, objected to the 14-day standard because a licensee may not learn of the change when it occurs. Ex. 47. The Department rejected Cullen's objection noting that the 14-day reporting period is consistent with the provisions of Minn. Stat. § 144A.06, which requires controlling persons who transfer a beneficial interest in a nursing home to notify the Commissioner of Health within 14 days of the transfer's occurance. A 14-day period is needed and reasonable. However, the Department should recognize the fact that a licensee may not learn about transfers made by persons not under its control. Therefore, it is recommended that subp. 3 be amended to require a report within 14 days after the licensee knew or should have known of the transfer, whichever occurs first." This will preclude assessing a monetary penalty on licensees who are unaware of ownership transfers between shareholders, for example, when the transfer occurs.

31. Subp. 3, Item B. Subpart 3B requires the licensee of a nursing home to appoint a licensed nursing home administrator "who is responsible for the operation of the home in accordance with law and established policies and whose authority to serve as an administrator is delegated in writing." Thomas W. Paul, Executive Director of Crestview Lutheran Home, stated that the rule should be amended to authorize a nursing home administrator to oversee other operations of a corporation--such as apartments and assisted living--provided that there are full-time managers in the other divisions and the nursing home administrator does not have day-to-day responsibility for the other operations but only oversight responsibility. Ex. 18. The Department rejected that

suggestion. It noted that under Minn. Stat. § 144A.04, subd. 5, nursing homes generally must have a full-time, licensed nursing home administrator to serve them. In the Department's view, the statute limits the ability of nursing home administrators to serve as administrators of other entities. The validity of that assertion need not be considered because it is not addressed by the rule. All the rule requires is that a nursing home administrator be appointed. The rule is consistent with the statute and was shown to be necessary and reasonable.

32. Subp. 3, Item C. Item C requires the licensee to inform the Department within five days after the termination or appointment of a nursing home administrator. When a licensed nursing home administrator is not immediately available to assume a vacant nursing home administrator position, the licensee must notify the Department and identify the name of the person temporarily in charge of the facility. The rule specifically states that a licensee cannot employ an individual as a permanent administrator until that individual qualifies for licensure under Minn. Stat. § 144A.04.

Item C reiterates, with only minor changes, current rule 4655.1200E (1993), and its need and reasonableness need not be reestablished in this proceeding. Nonetheless, public comments and suggestions should be considered. CPM suggested that the five-day notice be extended to 30 days or, at least, be clarified. She also said that the rule should authorize persons studying to become a nursing home administrator to act as a temporary administrator for up to one year. Ex. 47. CPM's second suggestion was properly rejected by the Department because acting administrators must have an acting administrator's license under Minn. Stat. § 144A.27. To clarify the rule, the Department adopted language reiterating that statutory requirement and also made grammatical changes suggested by Julie M. Vikmanis, Executive Director of the Board of Examiners for Nursing Home Administrators. The rule is necessary and reasonable, as amended, and the amended rule does not constitute a substantial change under Minn. Rules, pt. 1400.1100.

The Department didn't consider enlarging the five-day reporting requirement or clarifying whether it is a business day or calendar day requirement. Because the rule doesn't use the word "work days" it must be construed to mean calendar days under Minn. Stat. § 645.45(a). When a report is required within a fixed period of time, in computing the time when the report must be filed the first day is excluded and the last day of the prescribed or fixed period of time is included. When the last day of the period falls on a Saturday, Sunday, or legal holiday, it is omitted from the computation. Minn. Stat. § 645.15 (1994). Nonetheless, the Department should consider using the words "calendar days" to clarify the rule and should also consider further amendment to the first sentence making mailed notice effective on the date of mailing or the postmark date.

33. Subp. 3, Item F. This rule makes the licensee responsible for the provision "of evidence of adequate financing, property [sic] administration of funds, and the maintenance of required statistics." The rule reiterates the requirements in current rule 4655.1200, subp. 2I. Consequently, its need and reasonableness need not be established in this proceeding. The Department should, however, replace the word "property" (line 22, page 20) with the word "proper."

Although the language of subp. 3F as published in the State Register can be adopted because its need and reasonableness was previously established, the rule's intent is unclear. The ambiguity is whether the rule contains a substantive mandate or whether a licensee's responsibility for the "provision of evidence of adequate financing", for example, is described in some other rule which explains what evidence of financing must be provided, and to whom, and when the evidence must be provided. If the Department's view is that the rule contains a statement of behavior not clarified elsewhere, the Department should clarify it further. After all, violations of the rule can result in a penalty assessment under part 4658.0190. If penalties are to assessed, the rule should clearly state the licensee's responsibilities. How else will a licensee know what "required statistics" should be maintained or what constitutes the "proper administration of funds?"

As suggested by the Board of Examiners for Nursing Home Administrators (Ex. 71), the Department intends to insert a sentence from part 4658.0060, Item H at the end of subp. 3F. The pertinent sentence states:

> There must be financial resources at the time of initial licensure to permit full-service operation of the home for six months without regard to income from resident fees.

MAHA stated that cited language is ludicrous. It its view, there is no reason why a new facility should have the resources to operate six months without recognition of resident revenue. The Department's SONAR does not mention or discuss the reason for this requirement. In response to MAHA's comment, the Department stated that new facilities should have the financial resources to permit full-service operation for six months without regard to income from resident fees. The basis for the six-month requirement is unknown. However, the requirements are currently mandated under Minn. Rules, pt. 4655.1400C. Because this rule merely repeats the requirements in an existing rule, the Department is not required to reestablish its need and reasonableness.

Part 4658.0055, Administrator.

34. Subp. 2. Serve only one nursing home. This rule requires a nursing home's administrator to serve only one nursing home no less than 40 hours weekly and prohibits the administrator from also serving as the director of nursing, except when authorized by statute. The rule was criticized by many persons. William Ward, Administrator of Lakeside Community Home, stated:

> The proposal defines full time as "no less than 40 hours per week." This definition leaves no room for vacation, holiday, etc., nor does it leave room for averaging. Most administrators work well over 40 hours per week. In a slow week I often try to cut back a few hours in order to keep life somewhat in balance. (Ex: Follow a 50 hr. week with a 35 hr. week) That would now be technically illegal. I would suggest alternate language allowing for "an averaging of 40 hours per week including contractually allowed vacation, sick and holiday time."

Ex. 21. It was also suggested that the rule should recognize the fact that compensatory time can be taken and that the administrator need not be on site 40 hours weekly. Ex. 22. Other persons suggested that working 30 hours weekly or more be deemed full-time employment.

In response to these comments the Department proposes to amend the rule to state that full-time employment means no less than 35 hours' work weekly. It also proposes to add a new sentence stating that the administrator of a hospital with a C&NC unit may serve both units pursuant to Minn. Stat. § 144A.04. As a general rule, nursing home administrators must work full time under Minn. Stat. § 144A.04, subd. 5. Because the statute does not define full-time employment, the Department may do so. Blocker Outdoor Advertising Co. v. Minn. Department of Transportation, 347 N.W.2d 88 (Minn. Ct. App. 1984). The Department's decision to treat employment of 35 hours per week or more as full time is supported by public comments and was shown to be necessary and reasonable. The changes proposed by the Department do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Loren Ellery, Administrator of Divine Providence Health Center, and Jon Marcaccina argued that small nursing homes should not be required to have full-time administrators. Exs. 29 and 55. In spite of the problems small facilities and rural facilities may have in connection with the employment of a full-time administrator, the Department cannot alter the full-time standard generally required by Minn. Stat. § 144A.04, subd. 5.[2] Consequently, the persons who objected to compliance with the statutory requirement must abide by the rule until such time as the statute is changed.

The Department did not specifically address other comments requesting that the rule specifically mention acting administrators; that it recognize vacation leave, holiday time, and compensatory time; and that it recognize time spent by the administrator away from the nursing home. In its written response, the Department noted, however, that the rule is not intended to require the administrator to go without vacations or holiday time. It is apparently the Department's intention to permit administrators to take vacation time, holiday time, and compensatory time, and, in that sense, the requirement for 35 hours of weekly work should be considered an average number of hours administrators must spend performing their duties, whether on site or not. If the Department has a different intention, the rule should be clarified. Because acting administrators are administrators, they must comply with the requirements of rule.

35. Subp. 3. Administrator's absence; requirements. This rule states that a nursing home may not be left without competent supervision at any time and requires that someone having the authority to act in an emergency must

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2. The statute contains some exceptions. It provides that any nursing home of 25 beds or less the director of nursing services may also serve as the administrator. It also permits two nursing homes under common ownership having 150 beds or less and located within 75 miles of one another to share the services of an administrator.

always be left in charge of the facility. It prohibits the administrator from leaving the premises without giving information where the administrator can be reached and without delegating authority to a person at least 21 years of age and capable of acting in an emergency. The rule reiterates the requirements in current rule 4655.1300, subp. 3 and its need and reasonableness need not, therefore, be reestablished in this proceeding.

David F. Hagen, Administrator of Roseau Area Hospital and Homes, suggested that the rule should recognize established policies and procedures identifying the persons who meet the requirements of the rule in the administrator's absence. Ex. 20. William Ward stated that the word "and" (p. 21, Line 4) be replaced with the word "or" so that an administrator who is absent need not leave information where he can be reached if a competent person is left in charge. Ex. 21. Vern Silvernale, Administrator of Community Memorial Hospital and Homestead Nursing Home, made a similar comment. Ex. 59. Steven Chies questioned whether the administrator has to be within reach of a telephone or other communication device 24 hours-a-day even when on vacation or sick. Ex. 75. The Department did not address the merits of these comments but relied, instead, on the language in the current rule. Because the need and reasonableness of the current requirement must be assumed, the Department is not required to change the rule. Nonetheless, the comments mentioned above should be reconsidered. If a competent person is always in charge of a nursing home, whether it is the administrator or other person, the need for the administrator to be available at all times is highly questionable. Based on the record, the Administrative Law Judge recommends that the suggestion for replacing the word "and" with the word "or" be adopted. This would not constitute a substantial change in the rule and appears to be sensible. It apparently is the Department's intention not to require the administrator to designate a person to act in his place each time the administrator leaves the nursing home, but to recognize written policies which will identify the person in charge. If this is not the Department's intention, the rule should be clarified.

Part 4658.0060. Responsibilities of Administrator.

36. 4658.0060, Items A and B. Items A and B require nursing home administrators to maintain, complete and submit reports and records required by the Department and formulate written policies, procedures and programs for the operation, management and maintenance of the nursing home. Thomas W. Paul, Executive Director of Crestview Lutheran Home, stated that administrators do not perform these duties but insure that they are performed. Ex. 18. Similarly, G.H. Amble, Executive Director of Glenwood Retirement Village, stated that administrators only recommend policies and that sole responsibility for policy making resides in the board of directors. In spite of these comments, the Administrative Law Judge is persuaded that the rule originally proposed is necessary and reasonable. The rules do not require the administrator to personally perform each of the duties for which the administrator is responsible. Under the rules, the administrator is only required to ensure that the listed items are performed. Furthermore, as noted by the Department, the administrator is not charged with adopting policies but merely formulating them.

37. 4658.0060, Item F. This rule requires administrators to maintain a weekly time schedule showing each employee's name, job title, hours of work, and days' off. The schedule must be dated and communicated to employees. The

rule states that the schedule, timecards, and payroll records must be kept on file for three years and must be available to departmental personnel. MAHA recommended that the words "payroll records" be deleted from the rule. Ex. 46. CPM suggested that the rule refer to Department of Human Services rules on time and attendance reporting requirements or state that those standards are the ones that will be followed by the Department of Health. Ex. 47.

In the Department's view, documents showing the time worked by all employees is necessary. However, the Department does not intend to require a particular type of documentation containing that information. To clarify its intention, the Department intends to amend the third sentence of the rule to state:

> "The schedules and time cards, payroll records, or other written documentation of actual time worked and paid for must be kept on file in the home for three years and must be available to representatives from the department."

If documents kept for reimbursement purposes under rules of the Department of Human Services contain the necessary information, they are acceptable forms of written documentation under the amended rule. The rule, as amended, is necessary and reasonable and the amendment made does not constitute a substantial change under Minn. Rules, pt. 1400.1100 (1993). However, the Department should eliminate the requirement that the records must be available to representatives of the Department. All required documentation under the rules is available to the Department under Part 4658.0150.

38. 4658.0060, Item I. This rule requires the administrator to develop and maintain channels of communications with employees by distributing written personnel policies to employees, regularly scheduling meetings of supervisory personnel, having an employee suggestion system, and evaluating employee work performance. CPM questioned the necessity for the rule. Nonetheless, it reiterates requirements currently contained in part 4655.1400D (1993). As noted before, the Department is not required to establish the need and reasonableness of previously adopted rules which are merely being reenacted in this proceeding. Consequently, the merits of CPM's comments will not be addressed further.

Part 4658.0065. Resident Safety and Disaster Planning.

39. Subpart 1. Safety program. The rule requires nursing homes to have safety plans and programs. The safety plan must be included in the orientation and in-service training programs of all employees and volunteers. The Board of Nursing suggested several grammatical changes in the rule. Its Executive Director, Joyce Schowalter, suggested that the words "a nursing home" be replaced with the words "the licensee", that the words "must have" be replaced with the words "must implement", and that the rule specifically require temporary staff to receive training in the safety program because they might be required to deal with emergency situations and routine safety issues. Ex. 73. The Department did not respond to the suggestions, but may do so before the rules are finally promulgated. The proposed rule, which is consistent with current rule requirements, was shown to been necessary and reasonable.

40. Subp. 2. Security of physical plant. This rule requires that nursing homes have a method of insuring the security of exit doors leading directly to the outside when they are not directly observable from the nurse's station. In response to CPM's comments, the Department noted that the rule does not preclude "regularly staff [sic] areas" from being one method of ensuring the security of exit doors not under direct observation from the nurse's station. The Department didn't address the Board of Nursing's suggestion that the rule be rewritten to simply require that exit doors not directly visible from the nurses' station be secure at all times. In its comments, however, the Department has decided that observation is one method of securing exit doors. The rule proposed was shown to be necessary and reasonable.

41. Subp. 5. Drills. This rule states that "residents do not need to be evacuated except when a drill is planned in advance. CPM stated that it doesn't make any sense to evacuate nursing home residents in every drill and that the rule should specify that residents do not need to be evacuated unless there is an emergency. Ex. 47. Patricia J. Reller, Administrator of Ramsey Nursing Home, stated that the rule should be written to state that residents don't need to be evacuated "except when an evacuation drill is planned in advance." Ex. 38. Steven Chies submitted similar comments. Ex. 75. In response to these comments, the Department has decided to clarify subpart 5 by amending it to read as follows: "Residents do not need to be evacuated except when an evacuation drill is planned in advance." The amended rule was shown to be necessary and reasonable and does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.0070. Quality Assessment and Assurance Committee

42. Part 4658.0070 requires nursing homes to have a six-member quality assessment and assurance (QAA) committee which is responsible for taking steps to improve resident care by correcting deficiencies. The rule revises and expands current part 4655.1400G. Under federal regulations, nursing homes must maintain a QAA committee comprised of the director of nursing services, a physician designated by the facility and three other staff members. 42 C.F.R. § 483.75 (o)(1)(1993). The Department's rule follows federal regulations but also requires the administrator to be a committee member. It did so to ensure that any reports or recommendations of the committee will be seen by the administrator. The Department believes that information from the QAA committee will more likely come to the attention of the nursing home administrator if the administrator is a member, resulting in improvements in resident care. SONAR at 24.

Some persons objected to including administrators on the QAA committee (Exs. 17, 32) and some objected to specification of any QAA committee members. Exs. 18, 20. Others, like the Minnesota Alliance for Health Care Consumers and the Ramsey Nursing Home, supported the rule. Exs. 33, 38. The number and identities of persons who must be on the QAA committee is a policy decision the Commissioner can make, and the proposed rule reflecting that policy decision is necessary and reasonable. The fact that federal regulations do not include the administrator does not preclude the Department from doing so or requiring additional QAA members.

In response to public comments, the Department has decided to amend the rule to permit the medical director "or other physician designated by the medical director" to serve on the QAA committee. Also, it proposes to amend the rule so that the QAA committee does not need to represent "all" disciplines involved in resident care. These amendments were shown to necessary and reasonable and do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993). The Department chose not to modify the rule in response to comments suggesting that the consultant pharmacist be on QAA committee and to delete the examples of issues the QAA committee must address. The Department's decision on those issues involves reasonable policy choices.

Mr. Hagen of Roseau Area Hospital and Homes stated that part 4658.0070 is not appropriate for nursing homes operated as a department of a hospital. In his view, quality assurance activities should be coordinated throughout a joint facility. He said that resident care will suffer if a nursing home operated as part of a hospital is allowed or encouraged to participate independently in its own quality assurance and improvement activities. Ex. 20. The Department did not respond to this comment, but is clear that nursing homes which are attached to hospitals must have a QAA committee under federal regulations. Therefore, in spite of the difficulties that might be encountered in a particular case, compliance is required.

Part 4658.0080. Notification of Boards

43. This rule states that a nursing home must "notify the applicable professional board when a licensed health professional is providing inappropriate services, inadequate care, or fails to respond to the needs of the residents." Based on voluminous criticism of the rule, as written, the Department has decided to withdraw it.

Part 4658.0085. Notification of Change in Resident Health Status.

44. Under this rule, nursing homes must adopt and implement policies for determining when staff members should consult physicians, physician assistants, and nurse practitioners and when they must notify the resident's legal representative or family member of a resident's acute illness, serious accident, or death. The policies must have criteria which, at a minimum, establish notification times for certain resident accidents, significant changes in a resident's condition, significant changes in treatment, decisions to transfer or discharge a resident, and expected and unexpected resident deaths.

In response to comments made by Robert K. Meiches, M.D., President of the Minnesota Association of Nursing Home Medical Directors and Physicians, the Department proposes to amend the rule to require that the director of nursing services and the medical director or an attending physician be involved in the development of the policies required under the rule. Ex. 51. The rule, as amended, was generally supported by the public and was shown to be necessary and reasonable. Furthermore, the language changes made do not constitute a substantial change for purposes of Minn. Rules pt. 1400.1100 (1993).

The major criticism of part 4658.0085 relates to the exclusive authority of a licensed physician to pronounce death. The Board of Medical Practice and the Board of Nursing (Exs. 73, 79), argued that the rule inappropriately permits persons other than physicians to determine that a resident has died. The Administrative Law Judge is persuaded that under existing law, only physicians may pronounce death. However, the rule does not contain any language which authorizes physician assistants or nurse practitioners to do so even with a doctor's authorization. In its response, the Department made it clear that this rule must be construed and applied in a manner consistent with existing law regarding a physician's authority to pronounce death. It follows that nursing home policies must be consistent with existing law which only authorizes physicians to pronounce death. The rule was shown to be necessary and reasonable,

4658.0100. Employee Orientation and In-Service Education.

45. Subpart 1. Orientation and initial training This rule requires that all nursing home personnel receive documented instruction on the laws relating to their duties. Also, personnel must be informed of the nursing home's policies and procedural manuals must be readily available to guide them in performing their duties. The Board of Nursing suggested that the word "personnel" be replaced with the words "employees and temporary staff". The Department did not comment on that suggestion. The rule is necessary and reasonable as proposed.

46. Subpart 2. In-service education. This rule requires that nursing home employees receive in-service training to ensure their continuing competency.. The training must address areas identified by the QAA Committee and the special needs of the homes' residents. In response to written comments submitted by the Board of Nursing, the Department proposes to replace the word "in-service training" with the term "in-service education" and add a sentence requiring that the education include "rehabilitation for all nursing personnel to promote ambulation; aid in activities in daily living; assist in activities, self-help, maintenance of range of motion, and proper chair and bed positioning; and in the prevention or reduction of incontinence". The proposed amendments were shown to be necessary and reasonable and do not constitute substantial changes for purposes of Minn. Rules pt. 1400.1100 (1993). Training in rehabilitation for all nursing personnel is currently required under Part 4655.6800D.

47. Subpart 3. Reference materials. This rule states: "Textbooks, periodicals, dictionaries, and other reference materials must be available and kept current." This rule reiterates the requirements currently found in part 4655.6200, subp. 4. Consequently, its need and reasonableness need not be reestablished in this proceeding. Nonetheless, as noted by CPM, the rule is ambiguous because it's difficult to determine when a dictionary, for example, is current. Moreover, because the types of written materials a nursing home must maintain is not specified, it is questionable why a reference book which isn't current violates the rule if that reference book is not required to be kept. At a minimum, the Department should amend the rule by including some standard for determining when materials are "current" or require, instead, that nursing homes review the currency of their written materials at stated time intervals.

Part 4658.0110. Incident and Accident Reporting.

48. This rule requires that a "detailed incident report of any accident or injury and the action taken must be completed immediately." In response to public comments regarding the scope of this rule, the Department proposes it to amend it to read as follows: "A detailed incident report of any accident or injury to a resident and the action taken must be completed immediately." The amended rule makes it clear that recordkeeping relating to employee incidents are not covered. The rule was shown to be necessary and reasonable and the amendment made does not constitute a substantial change for purposes of Minn. Rules pt. 1400.1100 (1993).

In its post-hearing comments on this part, the Department stated that the rule is not limited to reports by nursing staff. If that is the intent, the Department should consider further amendment requiring all employees to report accidents or injuries which occur and requiring the nursing home to complete a detailed incident report of those accidents or injuries as well as the action taken immediately after learning of the accident or injury.

Part 4658.0115. Work Period.

49. This rule states that an employee cannot work for more than one consecutive work period of more than 12 hours' duration except in a documented emergency. Limiting the number of consecutive hours employees can work is directly related to the health and well-being of residents, and the rule limiting the number of consecutive hours employees can work was shown to be necessary and reasonable. Several persons suggested, however, that the rule be amended to clarify how nursing homes must document emergencies requiring employees to work more than 12 consecutive hours. Exs. 18, 24, 58. The Department indicated that documentation means a written record of the emergency and that documentation on the work schedule will be sufficient. Since that is the Department's intention, it should consider amending the rule stating that documentation can be made in that manner.

Part 4658.0120. Employee Policies

50. Subpart 1. Keys. This rule requires that the person in charge of a nursing home on each shift must be able to open all doors and locks in the nursing home except the doors and locks to the business office. The rule reiterates, with only minor changes, the language in Part 4655.2000, subp. 2. The changes made to the current rule were shown to be necessary and reasonable.

Several persons criticized the scope of the rule. They questioned the need for the person in charge to have access to such areas as the in-house pharmacy (Ex. 72), QAA incident reports and documents (Ex. 57), storage areas (Ex. 27), and other areas. The Department concluded that it is unnecessary to limit the rule because it is unaware of any instances where the current rule has caused problems. Due to a fire or other unforeseen emergencies, it may be necessary for the person in charge to have access to locked areas. The rule doesn't preclude the nursing home from putting QAA records in a locked cabinet. Furthermore, it can take steps to assure that responsible persons are placed in charge. The Department's decision to retain the rule as proposed is reasonable.

Part 4658.0130. Employees' Personnel Records

51. This rule requires a current personnel file for each employee and specifies the contents of the files. It is essentially the same as the current rule. Minn. Rules, pt. 4655.4400. Consistent with 42 U.S.C. § 12112(d)(3)(B), medication information must be treated in a confidential manner and may not be included with the employee's general personnel record. In its post-hearing comments, the Department made a change in the rule to clarify the illnesses for which records must be kept. The rule, as amended, is necessary and reasonable and the amendment which will be made does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993). However, because the Department indicated that employee records must be maintained for three years, it should amend the rule further to specify the retention period and the point at which the retention period begins to run. That is, whether it is for the most recent three-year period or begins to run when the employee is hired or discharged. Also, the Department should eliminate the requirement that personnel files must be available to the Department. Under Part 4658.0150, all records, including personnel records, are available to the Department. It is confusing to have duplication because questions may be raised about the Department's access to any records which have not been specifically made accessible to the Department. See Part 4658.0060F supra.

Part 4658.0135. Policy Records.

52. Subpart 1. Availability of policies. Initially, this rule stated that all "policies and procedures adopted by the home must be placed on file and be made available upon request to nursing home personnel, residents, and family members. It is an expansion of the rule currently found at 4655.4200 which only requires a home to make its policies and procedures accessible to personnel. A large number of persons objected to the rule. For the most part, they objected to its breadth and scope. They are concerned that the rule requires nursing homes to provide data unrelated to patient care, that their proprietary interests in policies and procedures will be impaired, and that the rule may encourage disputes, lawsuits and fishing expeditions. In response to these comments, the Department proposes to amend the rule to read as follows:

> "All policies and procedures directly related to resident care adopted by the home must be placed on file and be made available on request to nursing home personnel, residents, their guardians or their chosen representatives.

The rule, as amended, was shown to be necessary and reasonable and the amendments made do not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993). As noted by the Department, under Minn. Stat. § 144.651, subd. 4, current facility policies must be available to residents upon request. The only exception under the statute are policies, if any, which are protected under Minn. Stat. Chapter 13 and section 626.557, relating to vulnerable adults.

Presumably, a nursing home's policies and procedures are designed to enhance resident care and treatment. Resident access to those policies and procedures might reveal that the resident's care and treatment is inconsistent with them. It follows that access may identify shortcomings in a resident's care and lead to improvements. The rule is clearly necessary and reasonable for that reason. MAHA is dissatisfied with the Department's amendments to the rule. It still believes that a nursing home's policies and procedures are proprietary documents. However, it failed to discuss the relevant provisions of the Minnesota Uniform Trade Secrets Act, Minn. Stat. § 325C.01, et. seq. and failed to show that nursing home policies and procedures are protectable trade secrets under that Act. It is difficult to understand how required policies and procedures constitute trade secrets given the language in section 144.651, subd. 4 and the fact that, to a substantial degree, a nursing home's costs of preparing those policies and procedures are reimbursed by the Department. Even if the policies and procedures are trade secrets, MAHA failed to show that it's members are unable to take steps to protect their proprietary interests even if the documents must be disclosed under the rule.

4658.0140. Type of Admissions

53. Subp. 1. Selection of residents. This rule authorizes specified nursing home staff to exercise discretion in the type of residents admitted to the home under its admission policies. It is nearly identical to the language of current Part 4655.1500. The only difference is that the new rule also makes the medical director a participant in deciding whether a resident will be admitted. Interested persons generally support the rule as amended, and it is concluded that the rule is necessary and reasonable. The Department decided, based on comments made by the Board of Nursing, to amend the rule to state that the administrator, in cooperation with the director of nursing services and the medical director, is responsible for "the admission of residents" to the home. The clarifying language does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

54. Subp. 2. Residents not accepted. This rule states that residents cannot be admitted or retained if the home cannot provide the care needed because of the resident's known "physical, mental, or behavioral condition." It goes on to state that residents who are denied admission must be informed of the reason for denial. The latter requirement is new. Several persons objected to the new requirement that applicants for residency be informed of the reason for the denial of their admission. Exs. 17, 26, 27. Others expressed concern about the amount of documentation that must be maintained to show compliance with this part. Ex. 58. In spite of these objections, it is concluded that the rule is necessary and reasonable.

The St. Cloud Area Legal Services Association (Ex. 50) expressed concerns regarding the language which requires that residents for whom care cannot be provided in keeping with their physical, mental and behavioral conditions cannot be admitted. Similar concerns were expressed by the Legal Aid Society of Minneapolis. Ex. 74. Both believe that the rule, or nursing home practices under the rule, may violate the Americans with Disabilities Act (ADA), section 504 of the Rehabilitation Act, the Fair Housing Act, and the Minnesota Human Rights Act. They argued that nursing homes must make reasonable accommodations for elderly residents in determining whether they can provide care. They also suggested that the rule be amended to specifically prohibit illegal discrimination.

In spite of these criticisms, the Department chose not to amend the rule. Because the scope of various federal and state laws relating to discriminatory practices have not been thoroughly addressed or argued, consideration of the rule's compatibility with those federal and state laws is not ripe for decision in this proceeding. Providers should be alerted, however, to the fact that they cannot refuse an application for admission on any grounds which violate federal and state laws including the Minnesota Human Rights Act, the Americans with Disabilities Act or other state and federal enactments relating to disabled persons. Nursing homes are encouraged, therefore, to review those federal and state laws and adopt admission policies consistent with them. Furthermore, the Department should preface the language in subp. 2 with the words "unless otherwise provided by law, including laws against discrimination, . . . This would put nursing homes on notice that other laws may be relevant under the rule.

Part 4758.0150. Inspection by Department.

55. Part 4658.0150 requires that all areas of the nursing home and all records relating to the care and protection of residents, including resident and employee records, must be available for inspection by the Department at all times. The rule is consistent with the rule currently found in Part 4655.2300 and its need and reasonableness need not be reestablished in this proceeding. Dr. Mark Leenay, M.D., stated that rule is inconsistent with federal regulations because QAA committee members are the only persons who can have access to incident reports and peer review and QAA documents. That argument lacks merit. Under 42 C.F.R. § 483.75(o)(3), the state may have access to those records to the extent that disclosure is related to determining if a QAA committee has compiled with the requirements of "federal regulations." Hence, the Department has authorization for access for limited purposes.

Part 4658.0190. Penalties for Administration and Operations.

56. Part 4658.0190 specifies the penalty assessments that will be made for violations of Parts 4658.0050 through 4658.0155. Under Minn. Stat. § 144A.10, the Department has authority to assess penalties for noncompliance with its rules. The amount of the penalty assessments for rules which were previously adopted and which have only been renumbered or editorially revised, have not been changed. The Department is not required to reestablish the need and reasonableness of those penalties. Other, new rule requirements for which penalties have been proposed were shown to be necessary and reasonable.

Under Item D, a $100 fine is specified for violations of Minn. Rules, pt. 4658.0050, subp. 3, Items G and H, among other things. However, as noted by the Board of Examiners for Nursing Home Administrators, there are no such rule items. The Department should correct the rule (page 28, line 22) accordingly.

Part 4658.0300. Use of Restraints.

57. Subp. 1. Definitions. This rule defines the terms "physical restraints", "chemical restraints", "discipline", "convenience", "emergency

measures", and "involuntary seclusion". The defined words appear in federal guidelines[3] (Guidelines) adopted by HCFA to clarify the provisions in 42 C.F.R. § 483.13(a) (1993), which states:

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3. See Appendix P, "Guidelines to Surveyors-Long-Term Facilities", State Operations Manual, U.S. Health Care Financing Administration (HCFA), April 1992.

> Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms.

The Department adopted a grammatical change in the rule suggested by the Minnesota Board of Nursing but rejected other suggestions pertaining to the language in subpart 1. It presented affirmative evidence establishing the need and reasonableness of subpart 1. The grammatical change made to that rule does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

Several persons objected to the use of definitions based on HCFA guidelines. Jenean Erickson argued that the use of those Guidelines is inappropriate because they can change and are not binding regulations. Ex. 27. CPM argued that using the Guidelines would expose facilities to "double adverse action". Ex. 47. It is not unreasonable to use federal guidelines in drafting state rules. In fact, doing so, makes sense even if the guidelines are not binding regulations and might be changed in the future. Any rule the Department might adopt in this proceeding could be impacted by future changes in federal law, changes in technology, or changes in medical practice.

Steven Chies argued that the language used to define "physical restraints" is inconsistent with federal law because his understanding is that resident alarm systems or other devices to restrict movement are restraints. The Guidelines contain the same language as the Department's rule regarding devices which trigger electronic alarms to warn staff that a resident is leaving a room. The Guidelines state that such devices are not, in and of themselves, restraints. Guidelines, at P-76. Electronic alarms which do not restrict movement are not restraints.

Two individuals suggested that subpart 1, Item E, relating to involuntary seclusion, be amended to set a limit on the duration of a resident's seclusion. The Board of Nursing suggested a period up to 24 hours. Ex. 73. Iris C. Freeman, of the Minnesota Alliance for Health Care Consumers, also suggested that certain "bottom line" timeframes should be adopted. Exs. 33, 76. The Department did not specifically address these comments. It is a necessary and reasonable policy decision not to fix a maximum duration because the circumstances involved can vary significantly from case to case. However, the Department must have intended that nursing homes who place a resident in involuntary seclusion develop a plan of care to meet the resident's needs in a reasonably expeditious manner and it would be preferable if a specific timeframe were set. Alternatively, it might require that the staff develop a plan of care to meet a secluded residents' needs expeditiously.

58. Subp. 1. Item D. This rule defines the word "convenience" as follows:

> "Convenience" means any action taken solely to control resident behavior or maintain a resident with a lesser amount of effort that is not in the resident's best interest.

The definition is the same is that contained in HCFA guidelines (P-76). MAHA stated that the definition is vague and ambiguous. It noted that the words "with a lesser amount of effort" and "not in the resident's best interest" are not understandable. MAHA's argument isn't persuasive. That part of the definition following the word "or" (P. 30, line 14) isn't impermissibly vague because it doesn't require facilities to guess at its meaning. The language MAHA criticized, although awkward, is understandable. It states that nursing homes cannot use restraints on a resident simply to make caring for the resident easier if the use of restraints is not in the resident's best interests. The words "best interest" are not further described, but apparently mean a resident's ability to attain or maintain the highest practicable physical, mental, and psychosocial well- being. See Minn. Rules, pt. 4658.0050. If the Department has some other standard of determining a resident's "best interests" it should clarify the rule further.

59. Subp. 3. Emergency use of restraints. If a resident exhibits behavior which threatens the health or safety of other residents or persons, the rule requires that the nursing home take temporary, emergency measures to protect the other residents and persons and to immediately call a physician. If restraints are needed, they may be applied only upon the physician's order. That order must specify the duration and circumstances under the which the restraint can be used. The restrained resident's legal representative or an interested family member must be notified when temporary emergency measures are taken. Approximately five individuals commented on the proposed rule, but the comments were not of significant, substantive import. However, in response to the comments, the Department proposes to make some predominantly grammatical changes to the rule. The Department established the need and reasonableness of the rule, as amended, and the changes proposed do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

60. Subp. 4. Decision to apply restraint. This rule states that the "decision to apply a restraint must be based on the assessment of each resident's capabilities and an evaluation of least restrictive measures." It also requires that the restraint be used in accordance with the plan of care and the comprehensive resident assessment and sets forth tasks nursing homes must do for residents placed in restraints. In response to public comments, the Department proposes to change the body of subpart 4 to read as follows:

> The decision to apply a restraint must be based on the comprehensive resident assessment. The least restrictive restraint must be used and incorporated into the comprehensive plan of care. The comprehensive plan of care must allows [sic] for progressive removal or the progressive use of less restrictive means. Nothing in this

part requires a resident to be awakened during the resident's normal sleeping hours strictly for the purpose of releasing restraints. For a resident placed in a restraint, the nursing home must obtain an informed consent and obtain a written order from the attending physician. At a minimum, for a resident placed in a physical restraint, the nursing home must also: . . .

The amended rule was shown to be necessary and reasonable and does not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

The Legal Aid Society of Minneapolis, Inc. suggested that subpart 4 be amended to require the physician to see the resident within three hours after the initiation of a restraint and that the maximum duration of any individual order for restraint be set at 24 hours. The Department did not adopt this suggestion because the proposed rule reflects HCFA Guidelines (P-76, 77). No law currently requires the language proposed by the Legal Aid Society and the Department is not required to adopt the language changes it suggested.

61. Subp. 4, Item C. As originally proposed, this rule required the nursing home to check a resident in restraint every 30 minutes. Four individuals objected to this requirement. See, e.g., Ex. 46. However, the requirement is consistent with proposed federal certification language. Furthermore, there are significant risks associated with the use of restraints. The Department's decision to require that restrained residents be checked every 30 minutes is a necessary and reasonable policy decision given the health risks involved in the use of restraints.

62. Subp. 4, Item E. This rule requires that residents in restraints be given an opportunity for motion, exercise and elimination for not less than 10 minutes each two-hour period during which a restraint is employed. Several persons objected to this requirement. MAHA recommended that the ten-minute requirement be deleted because subjecting residents to ten minutes of motion, exercise and elimination every two hours could be unnecessarily exhausting. MAHA fears that surveyors will interpret the rule to require the release of restraints and resident movement for at least ten minutes. The Department did not specifically respond to MAHA's comment. However, the rule only requires that residents be given an "opportunity" for motion, exercise, and elimination. It does not require ten minutes of movement which would unnecessarily exhaust a resident. The rule proposed was shown to be necessary and reasonable.

Part 4658.0350. Penalties for Use of Restraints.

63. This rule sets forth the penalties which will be assessed for violations of Part 4658.0300. MAHA objected to the $500 per day penalty proposed for failing to check residents in restraint every 30 minutes. In its view, HCFA's failure to require checks every 30 minutes suggests that the failure to do so does not present an imminent risk of harm to residents. Although the failure to check a resident every 30 minutes might not, in a particular case, create an imminent risk of harm or jeopardize the health, treatment, comfort, or safety and well-being of nursing home residents in restraints, there are health risks involved in the use of restraints and the

Department has decided that the failure to check every 30 minutes could subject residents to a risk of harm. The Department's policy decision on this point was shown to be necessary and reasonable.

Part 4658.0400. Comprehensive Resident Assessment.

64. Subpart 1. Assessment. This rule requires nursing homes to conduct a comprehensive assessment of each resident's needs. It must describe the resident's capability to perform daily life functions and the resident's significant impairments in functional capacity. The assessment must be used to develop, review, and revise the resident's comprehensive plan of care. The Minnesota Nurses Association stated that this part should assign responsibility for the assessment. It suggested that the director of nursing be assigned that responsibility because assessments are essentially nursing assessments as defined in the Nurse Practice Act. Ex. 68. The Board of Nursing also stated that the director of nursing services should be responsible for the assessment. Ex. 73. In addition, the Board of Nursing stated that a nursing assessment of the actual or potential health needs of a resident is one of the major functions and responsibilities of a registered nurse under Minn. Stat. § 148.171(3). In the Board's view, the Department's rules must recognize that the nursing assessment is one of the primary functions of a registered nurse and cannot be deleted to others. The Board also stated that an additional sentence should be added to the rule stating that a "nursing assessment is part of the comprehensive resident assessment and is conducted in accordance with the legal scopes of practice of licensed and unlicensed personnel." The Department rejected these suggestions. It stated that it does not wish to limit responsibility to the director of nursing. It also stated that it isn't necessary to specifically state that a nursing assessment is part of the comprehensive resident assessment because a nursing assessment is required under the Nurse Practice Act. In the Department's view it is unnecessary to repeat requirements of the Nurse Practice Act in the proposed rules. The proposed rule was shown to be necessary and reasonable. Nonetheless, the Board of Nursing pointed out that there has been confusion about the term "assessment" in reference to compliance with federal regulations. Therefore, the Department should reconsider the Board's recommendation to specifically state whether the nursing assessment is part of the comprehensive resident assessment.

65. Subp. 2. Information gathered. This rule lists the information that must be included in the comprehensive resident assessment. Required information includes the resident's medically defined conditions and prior medical history; medical status measurement; physical and mental functional status; sensory and physical impairments; nutritional status and requirements; special treatments or procedures; mental and psychosocial status; discharge potential; dental condition; activities potential; rehabilitation potential; cognitive status; and drug therapy. In response to public suggestions, the Department proposes to amend the rule to include "resident preferences" in the list of information that must be gathered. The rule, as amended, was shown to be necessary and reasonable and the amendment made does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

66. Subp. 3. Frequency. This rule requires that a comprehensive resident assessment be conducted within 14 days after the date of admission, after a significant change in the resident's physical or mental health, and at

least every 12 months. MAHA suggested that the words "significant change" be clarified (Ex. 46) and the Board of Nursing recommended that the word "promptly" be replaced with the words "within 48 hours or sooner." Ex. 73. The Department has decided to replace the word "promptly" with the words "within 14 days" but decided not to eliminate or further clarify the words "significant change". The rule proposed was shown to be necessary and reasonable and the amendment made does not constitute a substantial change. The requirement for an assessment following a "significant change" in the resident's condition is required under federal regulations. 41 C.F.R. § 483.20 (b)(4). Although the standard requires a nursing home to exercise its judgment, the rule is not unnecessarily vague and the Administrative Law Judge is not persuaded that a significantly clearer rule is feasible given the wide range of changes which might occur.

Part 4658.0405. Comprehensive Plan of Care.

67. Subpart 1. Development. This rule requires the development of a comprehensive plan of care for each resident within seven days after the comprehensive resident assessment is completed. The plan must list measurable objectives and timetables for meeting goals set to address the needs identified in the residents comprehensive assessment. The Board of Nursing suggested that the rule be amended to state that the care plan must be developed by professionals as determined by the resident's needs. Ex. 74. The Board of Nursing made a similar comment. It suggested that the director of nursing be required to coordinate development of the comprehensive plan of care. Other suggested that the rule be rewritten and clarified. Ex. 27 and 46.

In response to these comments, and others, the Department has amended the language in subpart 1. The amendments require the comprehensive plan of care to be developed by an interdisciplinary team, include an individual abuse prevention plan, and be revised by the interdisciplinary team at least quarterly and within seven days of any revision in the comprehensive resident assessment. The rule, as amended, was shown to be necessary and reasonable and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.0445. Clinical Record.

68. Subpart 1. Unit record. Under this rule, a resident's clinical record must be started at admission and incorporated in a central unit record system. The clinical record must identify the resident, contain a record of resident assessments, the comprehensive plan of care, progress notes on the implementation of the care plan, and a summary of the resident's discharge condition. The rule does not require that the resident record be kept at any particular place and was shown to be necessary and reasonable.

69. Subp. 2. Form of entries and authentication. This rule requires the timely, accurate, and complete collection of unit record data. Entries must be authenticated and dated by the person making them. All entries must be made as soon as possible after the relevant observation or treatment. When authentication is done electronically or by rubber stamp, the nursing home must have safeguards to prevent unauthorized use. The rule specifically

permits nursing assistants to document in the nursing notes if the nursing home has a policy authorizing them to do so. In response to public comment, the Department proposes to amend the rule to address the requirements which apply when nursing homes use an electronic, paperless means of storing the clinical record. The Department also proposes to amend the rule to permit the use of a rubber stamp only if the licensing rules for that health care professional authorize doing so. The rule, as amended, is necessary and reasonable, and amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

70. Subp. 3. Classification systems. This rule states that all "diagnoses and procedures must be accurately and comprehensively coded to ensure accurate medical profiles." Two commentors questioned the meaning of the words "comprehensively coded." Others noted that health information management professionals are trained in the "Intentional Classification of Diseases, Clinical Management" (9th ed.) (ICD-9-CM) conventions, guidelines, and practices. Under them, the words "comprehensively coded" simply mean to code to the highest degree of specificity possible. Ex. 62. Because health information management professionals understand the meaning of the words "comprehensively coded" the Department elected not to further define those words in the rules. The rule was shown to be necessary and reasonable.

71. Subp. 4. Admission information. This rule lists the information that must be collected and maintained for each resident upon admission. Among other things, the nursing home must obtain the resident's legal name, address, social security number, gender, marital status, birth information, date of admission, religious affiliation, hospital preference, and physician name. Interested persons question the need to obtain a resident's social security number and the date and place of birth. Others suggested clarification of the language relating to a resident's religious preferences. The date and place of birth are important pieces of information. Sometimes, software systems use the date of birth as the main patient identifier. The place of birth is often valuable information in the study and research of diseases. Based on the comments that were submitted, the Department made a minor change to religious information concerning residents, but made no other changes. The rule, as amended, was shown to be necessary and reasonable, and the amendment made does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993). It should be noted that when the nursing home is unable, with reasonable effort, to obtain information which is required to be in the clinical record, it may simply insert the word "unknown."

Part 4658.0450. Clinical Record Contents.

72. 4658.0450, Item B. This rule states that each resident's clinical record must include the resident's "temperature, pulse, respiration, and blood pressure (taken at least weekly), and pertinent observations as often as indicated by the condition of the resident. . . ." MAHA suggested that vital signs should only be required monthly unless the resident's condition makes more frequent measurement necessary. Ex. 46. In response to that comment and comments submitted by CPM, the Department decided to amend the rule to simply require temperature, pulse, respiration and blood pressure. It will, however, retain a requirement to check the vital signs on a weekly basis under Part 4658.0520, subp. 2, Item I. The rule, as amended by the Department, was shown to be necessary and reasonable and the amendments made are not substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

73. 4658.0450, Item E. This rule states the clinical record must contain the "observations, assessments, and interventions provided by all disciplines responsible for care of the resident. . . ." The Minnesota Nurses Association suggested that the rule should be amended to exclude nurses' notes. Ex. 68. In its view, nursing notes should be located where nursing care is recorded and not with the notes from other disciplines. The Board of Nursing suggested that the rule should refer to the comprehensive resident assessment and the comprehensive plan of care, rather than the word "assessments." Ex. 73. The Department rejected most of the suggestions made regarding this rule. It noted that nurses' notes are part of the clinical record and that the word "assessment" as used in this rule, does not refer to the comprehensive resident assessment or the comprehensive plan of care. The covered assessments are those made by persons responsible for making assessments under the standards of practice applicable to the person making the assessment. The Department did decide, however, as MAHA suggested, to exclude confidential communications with religious personnel from the rule, as required by state law. The rule, as amended, was shown to be necessary and reasonable and the amendments made are not substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

74. 4658.0450, Item K. Under this rule, the clinical record maintained for a resident must include the "dates and times of visits by physicians, dentists, or pediatrists. . . ." MAHA stated that the need for recording the time for a visit is unnecessary and the Minnesota Nurses Association suggested that the rule cover more persons than the three health care practitioners mentioned. The Department rejected MAHA's suggestion because, in its view, it may be important to know the time of a visit. It noted, for example, the cause or effect of subsequent changes in a resident's condition might make that information necessary. The Department agreed, however, to expand the coverage of the rule to "all licensed health care practitioners." The rule, as amended by the Department, was shown to be necessary and reasonable, and the amendments made are not substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.0455, Telephone and Electric Orders.

75. 4658.0455, Item B. This rule states that orders received by telephone or other electronic means must be immediately recorded in the resident's record by an authorized person and countersigned by the health care practitioner at the time of the next visit. For the most part, comments addressed to this rule related to the time within which the health care practitioner must countersign an order received by telephone or other electronic means. In response to these comments, the Department decided that there should be a maximum time period by which such orders are countersigned. It decided that a 60-day period is appropriate because federal regulations require a physician evaluation at least once every 60 days. In addition, the Department made other technical amendments to the rule. The amendments made were shown to be necessary and reasonable and do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993). The amendment proposed by the Department, however, appears to exempt orders received by facsimile machine from being placed in the resident's record. It should consider further amendment which makes it clear that the exclusion for facsimile machines only applies to the counter signature requirement.

Part 4658.0470. Retention, Storage, and Retrieval.

76. Part 4658.0470 requires that resident records be preserved for five years following discharge or death. Clinical records must be stored in a safe and confidential manner. Off-site storage is permitted only for former residents. When records are stored off site, the nursing home must develop and implement policies and procedures to protect the confidentiality, retention and timely retrieval of records. Among other things, records stored off site must be retrieval within 24 hours. Some commentors supported the 24-hour requirement and others objected to it. Under federal regulations, clinical records must be "readily accessible." 42 C.F.R. § 483.75(l)(1)(iii). Furthermore, Bonnie Doering noted that federal regulations authorize a "resident" to obtain access to all the resident's records within 24 hours, excluding weekends and holidays. 42 C.F.R. § 483.10(b)(2)(i) (1993). The Department chose a 24-hour period on the recommendation of health information management professionals. It agreed, however, to change the 24-hour requirement to a period of "one working day." The rule, as amended, was shown to be necessary and reasonable.

Part 4658.0500. Director of Nursing Services.

77. Subp. 2. Requirement of full-time employment. This rule states that a nursing home's director of nursing services must be employed full time, no less than 40 hours weekly, and devote full-time attention to nursing services. The requirement for a full-time director of nurses is not new. Currently, under Part 4655.5700, subp. 3, nursing homes are required to have a full-time director of nursing services. The need and reasonableness of this requirement is not, therefore, an issue here.

Interested persons commented on the ability of nursing homes to obtain a waiver of the requirements in this rule and some expressed concern about the financial burdens placed on small, rural facilities to comply with the rule. In response to these and other comments, the Department proposes to amend subp. 2, consistent with prior amendments relating to administrators, and only require the director of nursing services to work no less than 35 hours weekly. The Department acknowledged that waivers from the requirements in this section are available if the proper demonstration can be made under Part 4658.0040. The changes made in the rule do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

78. Subp. 3. Assistant to director. This rule requires appointment of an assistant to the director of nursing services. The assistant is responsible for the director's duties in the director's absence and must carry out the director's responsibilities so that the director's duties are performed seven days weekly. The rule reiterates the provisions currently contained in Part 4655.5700, subp. 4 and its need and reasonableness need not be reestablished in this proceeding.

The Department rejected suggestions made by the Minnesota Board of Nursing and the Minnesota Nurses Association that the rule should require the assistant to be a registered nurse. In the Department's view, the rule does not conflict with Board of Nursing rules. Because the Department, the Board

of Nursing, and Minnesota Nurses Association did not adequately address the legality of the proposed rules, it will not be considered further. If the duties must be performed by registered nurses under the Nurse Practice Act or rules adopted by the Board of Nursing, nursing homes will be required to use registered nurses. That issue, however, must be decided in some other proceeding. It is not appropriate to address legal arguments that are raised but not properly briefed.

79. Subp. 4. Education. This rule requires any newly appointed director of nursing services to be educated in "rehabilitation nursing techniques, gerentology, nursing service administration, management, supervision, and psychiatric or geriatric nursing within twelve months after appointment. It replaces the requirements currently found in Part 4655.5700, subp. 5, which requires the director of nursing services to be trained in rehabilitation nursing techniques and have training or experience in areas such as nursing service administration or psychiatric or geriatric nursing.

CPM argued that the rule usurps the authority of the Board of Nursing because the Board sets continuing education requirements and licensure standards for nurses. In addition, it stated that the rule is unduly vague and ambiguous because it does not state how compliance will be surveyed, whether education taken as part of a nurse's training will qualify, and how recent the education must be. Ex. 47. The Board of Nursing, on the other hand, strongly supported the inclusion of educational requirements. It stated that the minimum educational requirement should be a baccalaureate degree followed by completion of specific course work. MAHA suggested elimination of the new terms "management, supervision, and gerontology" because the first two are implicit in the current requirement for education in "nursing service administration." According to MAHA, the second is a broad term which, to the extent applicable to nursing services, is included within "geriatric nursing." Ex. 46. The Minnesota Alliance for Health Care Consumers supported the new language. Ex. 33.

In response to the various comments submitted, the Department proposes to amend subp. 4 to read as follows:

> After the effective date of this part, a person newly appointed to the position of the director of nursing services must have completed courses in: rehabilitation nursing, gerontology, nursing service administration, management supervision, and psychiatric or geriatric nursing.

The Department showed that it is necessary and reasonable to amend the rule in the manner proposed and the amendment does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993). However, because the Department intends to accept seminars and workshops as qualified courses, the rule should say so. Furthermore, the Department should consider whether persons who have received training in rehabilitation nursing techniques and nursing service administration or psychiatric or gereatric nursing under the current rules, must repeat coursework in those areas when they change jobs.

Part 4658.0505. Director of Nursing Services; Responsibilities.

80. Part 4658.0505 reiterates, to a substantial degree, the provisions in Part 4655.5800, subp. 2, which enumerates the responsibilities of the director of nursing services. The new rule increases the director of nursing services' input into establishing staffing levels, authorizes the delegation of responsibilities to other nursing personnel, and eliminates the requirement that nurses accompany physicians when they are visiting residents. There were an abundant number of comments on Part 4658.0505. Most of them did not involve substantive criticism, but more technical, grammatical matters. The Department considered and evaluated all the comments submitted and proposed numerous changes to the rule. The rule, as amended, was shown to be necessary and reasonable, and none of the amendments proposed constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.0520. Adequate and Proper Care.

81. Subpart 1. Care in general. This rule is nearly identical to the language which currently appears in Part 4655.6400, subp. 1. Hence, its need and reasonableness need not be reestablished in this proceeding. Based on public comments received, the Department decided, however, to amend the rule to require that cares also be based on resident preferences and to permit residents to stay in bed if there is a written order from the attending physician or the resident prefers to stay in bed. The rule, as amended, was shown to be necessary and reasonable and the amendments made are not substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

82. Subp. 2. Criteria for determining adequate and proper care. This rule contains detailed criteria that must be used in determining whether a resident is receiving adequate and proper care. CPM stated that the items in this rule are unduly prescriptive and that all the criteria contained in the rule should be deleted. It is, however, necessary and reasonable for the Department set criteria for determining the adequacy of care provided to nursing home residents in order to fulfill its responsibility for protecting the health, safety, comfort, treatment and well being of nursing home residents.

83. Subp. 2, Item B. This rule essentially requires that residents have clean skin and be free of offensive odors. It states that a bathing plan must be part of each resident's plan of care and requires that residents confined to bed be given a complete bath at least every other day. Incontinent residents must be checked every two hours and must receive perineal care following each episode of incontinence. It goes on to specify other steps that must be taken to keep residents clean and odor free. Jenean Erickson stated that bathing plans should be provided by facility protocol and should not be a required part of the care plan. Ex. 27. Mr. Shreve, of MAHA, suggested that everything in Item B should be eliminated except the first sentence requiring clean skin and freedom from offensive odors. In addition, he stated that requiring residents confined in bed to have a complete bath every other day can create skin problems for a resident. In his view, this rule should be based on outcomes--cleanliness and freedom from offensive orders--rather than articulating specified steps that must be taken to achieve that outcome. CPM also suggested that everything following the first sentence of Item B be deleted but that the rule also include a requirement that a personal hygiene plan be made part of each resident's care plan. Ex. 47.

In response to public comments, the Department noted that under Part 4655.6800A patients confined to bed must currently bathe at least every other day. Furthermore, the Department stated that the bathing rule provides an opportunity for physical contact and stimulation and noted that products are available which do not contain soap and which promote soft skin and help retain moisture. The Department stated that due to the "importance of bathing, skin care and incontinence care," it has determined that the specificity contained in the rule is necessary to assure appropriate resident care. The Department did, however, make a grammatical change in the rule at the request of the Minnesota Board of Nursing. The rule, as amended by the Department, was shown to be necessary and reasonable, and the amendment made does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

84. Subp. 2, Items C-J. These rules relate to resident care. They require weekly shampoos, assistance with daily hair grooming, shaving, and oral hygiene. Measures must be used to prevent dry, cracked lips, and staff must give proper care and attention to the residents' hands and feet. Fingernails and toenails must be kept clean and trimmed, bed linen must be regularly changed, clean clothing must be available and residents must be dressed during the day, when possible. In addition, the resident's temperature, pulse, respiration and blood pressure must be monitored as often as indicated by the resident's condition, but at least every seven days, and the resident's height and weight must be recorded at the time of admission and every 30 days thereafter. Most of the requirements in these items are contained in existing rules. There were a number of comments objecting to the requirement for a weekly shampoo, the requirement for maintaining a resident's neat appearance, and requirements relating to monitoring a resident's vital signs. Nonetheless, most of the requirements in these Items are contained in current rules, and its need and reasonable need not be reestablished. Furthermore, where new language was added or changes were made, the Department established their need and reasonableness. It showed, for example, that the current rule, which only requires one shampoo monthly, is unacceptable and that a resident's height should be recorded on a monthly basis.

Part 4658.0525. Rehabilitation Nursing Care

85. Subpart 1. Rehabilitation nursing care. This rule requires that each nursing home have an active program of "rehabilitation nursing care" designed to assist residents to achieve and maintain their highest practicable, physical, mental, and psychosocial well being as set forth in the resident's comprehensive resident assessment and plan of care. The rule states that a nursing home must make continuous efforts to encourage ambulation and purposeful activities. It is patterned on and expands current requirements in Part 4655.5900, subp. 2.

Jenean Erickson, of Yorkshire Manor Nursing Facility, suggested that the last sentence of the rule should be amended to state that ambulation and purposeful activities should be made available pursuant to the care plan and not "continuously." Ex. 27. Mr. Sheve suggested that rehabilitation nursing care required under the rule should be "consistent with resident preferences." The Legal Aid Society of Minneapolis stated that the rule does not include the language in 42 C.F.R. § 483.25 et. seq. mandating that residents with mental health disorders receive appropriate treatment and care. They propose that the federal regulatory language be reiterated here.

The Department declined to refer to resident preferences in the rule because the Resident Bill of Rights, Minn. Stat. § 144.651, allows residents to refuse treatments including rehabilitation nursing care. In addition, the Department rejected the suggestions made by the Minneapolis Legal Aid Society. In the Department's view, it is enough to require nursing homes to help residents achieve the highest level of mental and psychosocial well being possible. The Department does not believe it is necessary to refer specifically to federal regulations which are binding on most nursing homes or other state laws which address the provision of mental health services, such as the Minnesota Comprehensive Adult Mental Health Act, §§ 245.461 - 245.486. The Department did agree, however, as recommended by Ms. Schowalter, to make a technical change in the rule. The rule, as amended, was shown to be necessary and reasonable, and the amendment made does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

86. Subp. 2. Range of motion. This rule requires nursing homes to have a program designed to prevent deformities through resident positioning and range of motion (ROM) exercises. Ms. Erickson stated that the rule should make it clear that ROM is effective only as assessed, needed, and "care planned." Ex. 27. The Board of Nursing suggested that the rule be amended to clarify that the director of nursing services must coordinate the development of a nursing care plan for rehabilitative nursing care. The Department accepted Ms. Schowalter's recommendation but rejected the changes proposed by others. The rule, as amended by the Department, was shown to be necessary and reasonable and the amendment made does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993). It appears that the concerns raised by Ms. Erickson can be addressed in the nursing care plan the director of nursing must coordinate under the rule.

87. Subp. 3. Pressure sores. This rule requires that nursing homes take steps to eliminate the development of pressure sores and provide residents who have them with necessary treatment to promote healing, prevent the infection, and prevent development of additional sores. The rule is identical to federal regulations relating to pressure sores. 42 C.F.R. § 483.25(c). Ms. Schowalter suggested language changes which require the director of nursing services to coordinate the development of a nursing care plan for dealing with pressure sores and require a physician's verification that pressure sores developing after a resident's admissions were unavoidable. The rule, as amended, was shown to be necessary and reasonable, and the changes made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

88. Subp. 4. Positioning. This rule requires that residents be positioned in good body alignment. When a resident is unable to change position, the resident's position must be changed by nursing staff at least every two hours, even if the resident is in bed, unless a physician has documented that repositioning every two hours is unnecessary or orders a different repositioning interval.

The Department's current rule only requires that nursing home staff encourage and assist bedfast patients to change positions at least every two hours. 4655.5900, subp. 3B (1993). Mr. Shreve, of MAHA, stated that some residents suffer from sleep deprivation under the Department's current rule requiring that residents be turned every two hours regardless of their condition. He suggested that language be added recognizing a resident's right to refuse repositioning. Jenean Erickson stated that the rule should address

totally or partially dependent residents and that a resident's position must be changed or modified as individually assessed and care planned when a resident is unable to change position without assistance. The Department stated that it does not believe it necessary to continuously repeat a resident's right to refuse treatment, including repositioning, under Minn. Stat. § 144.651, subd. 12. The Department noted that it has determined that the degree of specificity set forth in the rule is necessary and it declined to amend the language originally proposed. It noted that resident preferences can be addressed in the resident's comprehensive assessment and plan of care. Furthermore, for sleep deprivation, a physician can order a different time interval under the rule. The rule was shown to be necessary and reasonable.

89. Subp. 7. Nasogastric tubes. This rule requires that nursing homes ensure that residents who are independently able to eat enough, or who can do so with assistance, are not fed by nasogastric tubes or feeding syringes unless the resident's condition demonstrates that the use of a nasogastric tube or feeding syringe is unavoidable. Nursing homes must assure that residents fed by a nasogastric or gastrotomey tube or feeding syringe receive the services and treatment necessary to prevent aspiration phenomena, diarrhea, vomiting, and other problems, and restore, if possible, normal feeding functions. The rule is based on federal certification regulations which apply to most nursing homes. See 42 C.F.R. § 483.25(g). The only change is that the Department's rule also refers to feeding syringes.

MAHA suggested deleting this rule because it duplicates federal certification language and forces facilities to substitute their nursing judgment for the physician's medical judgment. Ex. 46. Ms. Cullen, of CPM, questioned whether the use of feeding syringes is an acceptable feeding mechanism for nursing homes. She suggested that they be prohibited. The Department determined, however, that they should be addressed in the rule. It also noted that physicians are supposed to be involved in the development of the resident's comprehensive care plan and that physicians can be consulted in making the comprehensive resident assessment. It believes that physicians will be involved in decisions regarding the use of nasogastric tubes or feeding syringes for individual residents. The rule proposed is necessary and reasonable.

90. Subp. 9. Hydration. This rule states that residents "must be offered and receive adequate water and other fluids to maintain proper hydration and health, unless fluids are restricted." The current rule--4655.6800C--requires only that fresh water and other fluids be available at all resident's bedsides unless fluids are restricted. Dr. Meiches stated that the rule should be construed to assure that residents have the right to refuse hydration. Ms. Cullen stated that CPM is concerned with the statement that residents must "receive" adequate fluids. As noted by the Department, the intent of the rule is not to override a resident's right to refuse fluids. When they don't, however, it is the nursing home's responsibility to ensure that fluids are actually received and not simply available, because some residents may need assistance in consuming them or encouragement to drink them. The rule proposed was shown to be necessary and reasonable.

91. Subp. 10. In-service. This rule states that nursing homes must provide an in-service training program in rehabilitation for all nursing personnel to promote ambulation; assist in activities of daily living; assist in activities, self-help, maintenance of range of motion, and proper chair and bed positioning; and in the prevention of incontinence. In response to

various comments the Department has decided to delete this subpart and combine the requirements for rehabilitation in-service with general in-service requirements contained in Part 4658.0100. The rule was shown to be necessary and reasonable.

Part 4658.0530. Assistance with Eating.

92. Subpart 1. Nursing personnel. This rule requires nursing personnel to assure that residents are served their prescribed diets. They must help residents who need assistance in eating when their meals are received. The assistance must be unhurried and be in a manner that enhances each resident's dignity. Self-help devices must be provided to foster the resident's independence in eating. Also, food and fluid intake must be observed and deviations reported to the charge nurse. Persistent, unresolved problems must be reported to the resident's physician. These requirements reiterate and slightly expand upon current requirements in Part 4656.6100, subp. 2 (1993). Consequently, the need and reasonableness of the rule need not be reestablished in this proceeding. In response to public comment, the Department proposes to clarify the person to whom deviations in food and fluid intake must be reported. Subpart 1, as amended, was shown to be necessary and reasonable, and the amendment made does not constitute substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

93. Subp. 2. Other Persons. Under this rule, individuals other than nursing personnel may assist residents with eating if certain conditions are met. Among other things, it must be safe, it must be permitted under the facility's policies, the resident must agree, the other person must have completed a training program for assisting residents with eating, the person must be under the direction of the director of nursing services, and there must be procedures for the other person to report observations made of the resident during mealtime. The rule, which applies to volunteers and other facility employees is based on current departmental policies and standards of practice.

Ms. Cullen, of CMP, noted that subp. 2 is broader than and inconsistent with federal regulations relating to individuals who may feed residents. The Department acknowledged the inconsistency. It stated, however, that until a change in the federal regulations occurs, certified facilities may not be able to utilize the provisions of the rule. Because the Department believes it is an appropriate standard, it refused an amendment suggested by CPM.

The Department agreed to make other changes to subpart 2 to make it clear that it applies to volunteers and nursing home personnel that normally don't do resident care and to allow family members to feed immediate relatives if permitted under nursing home policies. The rule, as amended, was shown to be necessary and reasonable and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993). However, it is recommended that the Department reconsider its decision not to conform this rule to federal regulations on the subject. The Department generally shouldn't adopt a rule in direct conflict with federal regulations governing the same types of facilities. Nursing homes can be mislead when state rules authorize activities which are forbidden under federal regulations applicable to the same facilities. The Department is authorized to adopt its own standards, but any standard which, in substance, has no effect due to federal regulations applicable to the same facility is of little benefit and only creates confusion. Therefore, the Department should conform the language of subpart 2 to federal regulations or limit its applicability to facilities which are not subject to those federal regulations.

94. Several persons stated that Item E should be amended to eliminate the requirement that the other person feeding a resident must be under the supervision of the director of nursing. To address these comments, the Department proposes to amend Item E to make it clear that the director of nursing can delegate supervision of the person feeding a resident to another nurse when the director of nursing is absent. The amended rule will state that the "director of nursing must be responsible for the monitoring of all persons, including family members, performing this [feeding] activity." The amendment proposed to clarify this point was also shown to necessary and reasonable and not to constitute a substantial change.

95. Subp. 3. Assistance with eating. In response to a recommendation made by Iris Freeman, Executive Director of the Minnesota Alliance for Health Care Consumers, the Department proposes to add a new subpart 3 to Part 4658.0530, which states that a "resident at risk of choking on food should be consistently monitored when they are eating so that timely emergency intervention can occur if necessary." The new language does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100, and was shown to be necessary and reasonable. However, the Department should consider when and how the risk of choking is identified and whether it must be indicated in the resident's comprehensive plan of care. Also, the words "consistently monitored" are ambiguous and should be clarified.

Part 4658.0700. Medical Director.

96. Subp. 2. Duties. This rule lists the duties of the nursing home's medical director, in conjunction with the administrator and the director of nursing services. In response to public comments, the Department has proposed amendments to Items A, D, F, and G. The rule, as amended, was shown to be necessary and reasonable and the amendments made, which were designed to clarify the rule, are not substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.0705. Medical Care and Treatment.

97. Subpart 1. Physician supervision. As originally published, this rule stated that nursing homes must insure that each resident has a licensed physician to supervise the resident's medical care and treatment. In response to comments from interested persons, the Department proposes to amend subp. 1 to read as follows:

> Subpart 1. Physician Supervision. A nursing home must ensure that each resident has a physician licensed by the Board of Medical Practice designated to authorize and supervise the medical care and treatment of the resident during the resident's stay in the nursing home, and another physician supervises [sic] the medical care of residents when their attending physician is unavailable.

The rule, as amended, was shown to be necessary and reasonable, and the amendment does not constitute a substantial change. However, the last clause of the rule, which contains new language, appears to contain some grammatical errors. It appears that the Department intends the last clause to state that a nursing home must assure that each resident has another available physician "to supervise" a resident's care when the resident's attending physician is unavailable. If so, it is recommended that the last clause be amended accordingly.

98. Subp. 2. Availability of physicians for emergency and advisory care. This rule states that nursing homes must provide or arrange for the provision of physician services 24 hours daily to handle emergencies and give advice. It goes on to state (Item B) that the name and telephone number of the emergency physician must be readily available. The Board of Nursing suggested that the director of nursing services should be responsible for maintaining the name and telephone number of emergency physicians. The Department declined to insert that requirement in the rules. In the Department's view, that responsibility can be placed on other persons as well. The Department did make a clarifying amendment to Item B, however, to make it clear that the name and telephone number of the emergency physician must be available at all hours. The rule, as amended, was shown to be necessary and reasonable, and the amendments made do not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

99. The Board of Nursing suggested that a third item should be added to subp. 2 which would require that nursing homes make sure that nursing personnel know how to obtain medical intervention when the emergency physician does not respond. The Department acknowledged that it knows of situations where nursing homes have had difficulty getting a timely response from an emergency physician and has decided to add a new Item C requiring nursing homes to develop a policy regarding emergency medical intervention. The new item will read as follows:

> C. The nursing home must develop and maintain policies and procedures regarding obtaining medical intervention when the resident's attending physician or the emergency physician does not respond to a request for medical care or is not available in a timely manner.

The new item was shown to be necessary and reasonable and does not constitute substantial change.

Part 4658.0710. Admission Orders and Physician Evaluations.

100. Subpart 1. Physical examination. This rule requires that residents have a "current admission medical history and complete physical examination by a physician, physician's assistant or nurse practitioner within five days before or seven days after admission." The Minnesota Chiropractic Association stated that the rule should be amended to authorize chiropractors to perform the admitting physical examination. Ex. 61. Its counsel, Scott L. Mayer, stated that many potential nursing home residents are regularly treated by a doctor of chiropractic and that clinical information which could be important

in managing the resident's care is frequently contained at the chiropractor's office. Mr. Mayer argued that while chiropractors cannot treat all medical conditions, they must be able to diagnose all presenting conditions and are authorized by the Minnesota Board of Chiropractic Examiners to perform physical examinations. The Department rejected that suggestion. It stated that physician assistants and certified nurse practitioners work under the supervision of a physician, so they should be allowed to conduct the admission history and physical examination. The Department went on to state that the "reason for the history and physical examination at the time of admission to a nursing home is to assure that the resident has a thorough assessment of their current medical condition, review of their medical history, and surveillance for any preventive measures. This is most appropriately done by the caregivers responsible for the resident's ongoing care. It provides caregivers with a comprehensive overview of the resident from which the comprehensive resident assessment and comprehensive plan of care can be developed and implemented. The history and physical should not be a pro forma exam conducted by a practitioner who is not directly involved in managing the resident's overall medical care." The rule proposed by the Department, for the reasons stated, was shown to be necessary and reasonable. The Minnesota Chiropractic Association failed to establish that the rule is inconsistent with state law.

101. Subp. 3. Frequency of physician evaluations. Among other things, this rule requires that a resident be evaluated by a physician at least once every 30 days for the first 90 days after the resident's admission and thereafter whenever medically necessary. One individual suggested that the rule should reiterate federal regulations requiring a physician evaluation every 60 days. Ex. 64. Two others strongly supported the current language. Ms. Cullen noted, on behalf of CPM, for example, that requiring physician visits when needed, not when mandated, will result in better resident care. Ex. 47. The rule proposed by the Department was shown to be necessary and reasonable.

102. Subp. 2, Item B. This rule states that required physician visits must be made by the physician personally, but permits the visits to be made by the physician personally or by the physician's assistant or certified nurse practitioner on an alternating basis after the initial visit. One person questioned whether the rule permits the practice of physicians to "round" for one another. Another individual indicated that her local clinic splits up nursing home residents between three facilities. She asked if the rule will require the clinic to "juggle" the residents between facilities so the residents will be in a facility their physician visits. The Department indicated that the rule would not require "juggling" of residents and permits physicians to "round" for one another. To accomplish that purposes it amended Part 4658.0705, subp. 1 to state that another physician can "supervise the medical care of residents when their attending physician is unavailable." The new language is consistent with federal certification requirements at 42 C.F.R. § 483.40(a). The rule amendment made by the Department was shown to be necessary and reasonable and does not constitute a substantial change.

Part 4658.0715. Medical Information for Clinical Record.

103. Part 4658.0715 sets forth the information physicians or their designees must provide for the clinical record. The information includes the

admission history and physical examination; admitting diagnosis; general medical condition, including disabilities and limitations; reports of physical examinations; instructions on the resident's total program of care; written orders for medications; progress notes; physical contacts with the resident's family or representative; advance directives; and the resident's condition on discharge or transfer, or cause of death. In response to public comments, the Department proposes to delete Item I, relating to physician contacts with a resident's family or representatives. The Department acknowledged that the information is difficult to obtain and does not directly affect the care provided to a resident. The Department rejected other, more technical amendments. The rule, as amended, was shown to be necessary and reasonable and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.0720. Providing Daily Oral Care

104. Subpart 1. Daily oral care plan. This rule requires that a daily oral care plan be established for each resident. In response to comments submitted by MAHA (Ex. 46) the Department has proposed an amendment to the initial paragraph of subp. 1 to make it clear that the plan is consistent with the results of the comprehensive resident assessment. The Department's intention apparently is to consider each resident's oral care needs as part of the comprehensive resident assessment and adopt a plan for daily oral care which is part of the comprehensive care plan. The rule, as amended, was shown to be necessary and reasonable, and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

105. Subp. 1, Item A. This rule requires that the resident's daily oral care plan must indicate whether the resident has natural teeth or wears removable dentures or partials and if the resident is able to maintain oral hygiene independently, needs supervision, or is dependent on others. MAHA suggested that the information set forth in Item A should be part of the comprehensive resident assessment rather than the daily oral care plan. The Department stated, however, that it is necessary to have the information in the daily oral care plan to ensure that nursing home staff providing oral care have the information available. The rule was shown to be necessary and reasonable as proposed.

106. Subp. 1, Item B. This rule requires nursing homes to provide residents with the supplies and assistance necessary to carry out each resident's daily oral care plan. The supplies must include toothbrushes, fluoride toothpaste, mouth rinses, dental floss, denture caps, denture brushes, denture cleaning products, and denture adhesive products. The language of the rule is consistent with federal regulations and is not intended to require that all these products be made available to all residents. The Department acknowledges that not all residents require all the items listed. The rule simply lists the supplies that must be available for residents who need them. The rule, as proposed, was shown to be necessary and reasonable.

107. Subp. 1, Item C. This rule requires that the daily oral care plan be made available to the attending dentist before each checkup. MAHA suggested that the rule only require the nursing home to provide the dentist with information about the resident's dental condition as set forth in the resident's comprehensive assessment. Michael J. Helgeson, a dentist, speaking

on behalf of the Long-Term Care Regulatory Reform Task Force, Dental Services Workgroup, stated that the daily oral care plan must be made available at the time of a checkup. Without this "outcome" measure and feedback from the dentist, he said neglected oral care could continue unchecked. Doctor Helgeson stated that the rule's requirement is a simple and not burdensome. Ex. 65. The Department chose not to amend the rule as suggested by MAHA. The rule proposed was shown to be necessary and reasonable.

108. Subp. 2. Labeling dentures. This rule requires nursing homes to label full and partial dentures with the resident's name or other identifiers within seven days of admission. Mr. Shreve, of MAHA, suggested that the paragraph be deleted. In MAHA's view, it is obsolete. Ex. 46. MAHA noted that manufacturers have labeled full and partial dentures for many years. He acknowledged that old dentures may not have labels, but he said that only dental labs have appropriate equipment to label them. Mr. Chies stated that it's not the nursing home's responsibility to label dentures on admission but the responsibility of the resident, the resident's guardian, or family members. Mr. Helgeson noted that while dentures are now labeled, many residents have dentures which do not contain a label. He stated that dentures are an expensive personal item which are easily misplaced. He also noted that labeling kits are readily available, simple, and inexpensive for nursing staff to use. The rule was shown to be necessary and reasonable as proposed.

Part 4658.0725, Providing Routine and Emergency Oral Health Services.

109. Subpart 1. Routine dental services. This rule states that routine dental services meeting needs of each resident must be provided to them. The services include dental examinations and cleanings, fillings and crowns, root canals, and adjunctive services provided to similar dental patients in the community at large, as limited by third-party reimbursement policies. Several clarifying language changes were suggested by interested persons. The Department declined to change the rule, however, it showed that the rule proposed is necessary and reasonable.

110. Subp. 2. Annual dental visit. Under this rule, each resident must be referred for an initial dental examination within 90 days after admission, unless the resident has received one within the previous six months. Thereafter, nursing homes must determine if a resident wants to see a dentist and make the necessary appointment on an annual basis. Under the rule, residents may refuse to be seen by a dentist. Following its customary practice in these rules, however, the Department rejected suggested amendments stating that residents have a right to refuse dental visits just as they can refuse medications and other treatments. It should be pointed out, however, that nursing homes must document any resident refusals or any problems encountered when a resident becomes uncooperative during these examinations. The rule is necessary and reasonable as proposed.

111. Subp. 3. Emergency dental services. This rule requires a nursing home to obtain or provide emergency dental services to residents. One individual requested that the rules clarify the meaning of a "dental emergency." The Department declined to clarify the words. It said it will rely on the definition of emergency dental services found in the guidelines implementing 42 C.F.R. § 483.55. The Guidelines define emergency dental services as "services needed to treat an episode of acute pain in teeth, gums,

or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention." Guidelines at P-180. The rule proposed was shown to necessary and reasonable. However, it is recommended that the Department refer to incorporate the Guideline definition of an emergency in the rules.

112. Subp. 4. Dental records. This rule sets forth the dental information that must be included in the clinical record. MAHA suggested deletion of the requirement that the clinical record contain medications administered at dental visits. Doctor Helgeson noted, however, that serious medical problems can result if this information in unavailable to the resident's nurses and physician. The Department rejected MAHA's recommendation for deletion of information relating to medications administered. The rule was shown to be necessary and reasonable.

Part 4658.0730. Nursing Home Requirements.

113. Subpart 1. Training. This rule requires that nursing home staff providing daily oral care must be trained and competent to do so. MAHA recommended that subp. 1 be deleted because nursing staff are precluded from performing duties for which they have not had proper and sufficient training under Part 4658.0510, subp. 4. However, the record shows that many nursing staff members called on to provide oral care have not received any training whatsoever. The Department determined that a training section should be included in this rule because oral care is a specialized form of training which may not be expected of all nursing home staff. Under the rule, nursing homes have discretion in determining the amount of training necessary to provide oral care. The rule was shown to be necessary and reasonable.

114. Subp. 2. Written agreement. This rule requires nursing homes to maintain a written agreement with a dental provider who will provide specified dental services to residents. CPM indicated that the rule should only require nursing homes to attempt to maintain a written dental provider agreement and that nursing homes should not be held liable if they are unable to find a dentist who will enter into such an agreement. As the Department noted however, nursing homes can obtain a waiver if it can demonstrate that compliance with the rule is not possible. The rule proposed was shown to be necessary and reasonable.

115. Subp. 5. List of dentists. This rule requires a nursing home to maintain a list of dentists in the service area who are willing and able to provide routine or emergency dental services for nursing home residents. The list must be readily accessible to nursing staff. CPM argued that this rule should be deleted. In its view, it imposes an unnecessary burden on nursing homes. The Department's current rule requires nursing homes to maintain the name and address of the emergency dentist at each nurse's location. The Department expanded that requirement to assure that staff are able to obtain care for residents when needed. The rule was shown to be necessary and reasonable.

Part 4658.0800. Infection Control.

116. Subpart 1. Infection control program. The rule requires nursing homes to establish and maintain an infection control program "designed to

provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection." In response to public comments, the Department proposes to amend the rules to read: "a nursing home must establish and maintain an infection control program designed to provide a safe and sanitary environment." The rule, as amended, was shown to be necessary and reasonable, and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

117. Subp. 2. Direction of program. This rule requires that a licensed nurse or a licensed physician be assigned responsibility for directing infection control activities in the nursing home. In response to suggestions that only registered nurses have the training necessary to direct infection control programs, the Department proposes to amend the rule so that registered nurses or licensed physicians must direct infection control activities. The rule, as amended, was shown to be necessary and reasonable and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

118. Subp. 4, Item A. This rule requires that a facility's infection control program contain surveillance procedures designed to establish nosocomial infection rates and identify the major sites of infection, their cause or origin, and associated complications. In response to public comments, especially those of infection control practitioners, and based on the professional standards of practice issued by the Association for Practitioners in Infection Control (APIC), the Department proposes to amend Subpart 4, Item A, to read as follows:

> Subp. 4. Policies and Procedures. The infection control program must include policies and procedures which provide for the following:
>
> A. Surveillance based on systematic data collection to identify nosocomial infections in residents;

The cited language was shown to be necessary and reasonable and does not constitute a substantial change for purposes of Minn. Rules pt. 1400.1100 (1993).

119. Subp. 4, Item E. Under this rule, the infection control policies and procedures must provide for an immunization program, a tuberculosis program, and resident care practices which will assist in the prevention and treatment of infections. Many infection control practitioners recommended deletion of the reference to employee tuberculosis programs because they are addressed in part 4658.0810. The Department rejected those suggestions because this rule relates to the development and implementation of employee health policies and infection control practices and refers to the applicable rule which must be followed as part of those employee health policies and infection control programs. The rule was shown to be necessary and reasonable.

120. Subp. 4, Item H. Under this rule, infection control policies and procedures must include "a system for review and evaluation of products which affect infection control, including items such as disinfectants, antiseptics, gloves, and disposable diapers. . . ." A large number of individuals

commented on the language of this item. In response to those comments, the Department proposes to amend Item H to make it clear that the listing contained in it is not all-inclusive and was not designed to establish a priority or mandatory listing, but merely to provide some examples of products which affect infection control. The rule, as amended, was shown to be necessary and reasonable, and the amendments made do not constitute substantial changes for purposes of Minn. Rules pt. 1400.1100 (1993).

Part 4658.0804. Persons Providing Services.

121. This rule states that no persons providing services to residents who have a communicable disease or infected skin lesion can work in a nursing home until a physician certifies that the person's condition does not endanger the health of residents and other staff. It goes on to state that the administrator may require any staff member to have a medical examination when there is a reasonable suspicion that the person has a communicable disease. In response to public comments, the Department proposes to amend this rule to clarify its meaning and to eliminate the requirement that a physician certify an employee or volunteer's ability to return to work without risk to residents and staff. The amended rule reads as follows:

> All persons providing services, including volunteers, with a communicable disease as listed in part 4605.7040 or with infected skin lesions must not be permitted to work in a nursing home unless it is determined that the person's condition will permit the person to work without endangering the health and safety of residents and other staff. The employee health policies required in part 4658.0800, subpart 4, item F, must address grounds for excluding persons from work and for reinstating persons to work due to a communicable disease or infected skin lesions.

The rule, as amended, was shown to be necessary and reasonable and the amendments made do not constitute substantial changes for purposes of Minn. Rules pt. 1400.1100 (1993).

Part 4658.0810. Resident Tuberculosis Program.

122. Subpart 1. Tuberculosis test at admission, and Subpart 2, Evaluation of symptoms. These subparts were the subject of a significant number of comments. Some individuals suggested that they should be deleted and replaced with language requiring nursing homes to comply with the most recent Centers for Disease Control and Prevention guidelines. Others suggested deleting the requirement altogether or they made suggested language changes to clarify the rule. In response to public comments and newly-issued guidelines from the National Centers for Disease Control and Prevention, the Department proposes to amend the rules to read as follows:

> Subpart. 1. Tuberculosis test at admission. A resident's clinical record must contain a report of a tuberculin test within the three months prior to admission or within 72 hours

after admission, administered in conformance with the general guidelines for surveillance and diagnosis as found in "Prevention and Control of Tuberculosis in Facilities Providing Long-Term Care to the Elderly; Recommendations of the Advisory Committee for Elimination of Tuberculosis", as issued by the Centers for Disease Control and Prevention, July 13, 1990. This guideline is incorporated by reference. It is available through the Minitex Library loan system. It is not subject to frequent change.

Subp. 2. Identifying, evaluating, and initiating treatment for residents who may have active tuberculosis. The nursing home must develop and implement policies and procedures addressing the identification, evaluation, and initiation of treatment for residents who may have active tuberculosis in accordance with Section II.C. of the "Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities, 1994", issued by the Centers for Disease Control and Prevention, October 28, 1994. This guidelines is incorporated by reference. It is available to the Minitex, library loan system. It is not subject to frequent changes."

The CDC guidelines are the most definitive statements of proper requirements relating to testing for tuberculosis and evaluating residents exhibiting systems of tuberculosis. Because final CDC guidelines were published after the Department proposed the rules involved in this proceeding, the Department, as suggested by several individuals, decided to reference those new CDC guidelines. Based all the evidence and argument available, the Administrative Law Judge is persuaded that the amended rule is necessary and reasonable and that the language changes made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993). CDC guidelines were addressed at the public hearing and in post-hearing comments.

Part 4658.0815. Employee Tuberculosis Program.

123. Part 4658.0815, as originally published, contained provisions to ensure that employees were screened for tuberculosis. The rules generally required employees to have a standard tuberculin test and contained procedures to follow if those tests are positive. Nursing homes were required to maintain written documentation of compliance and test employees exhibiting symptoms of tuberculosis. Several commentors suggested that the rule should be deleted because the federal and Minnesota Occupational Safety and Health agencies have mandated that nursing homes follow CDC recommendations for the prevention of tuberculosis. Because of those comments, and because CDC guidelines were adopted after the rules were originally proposed, the Department has rewritten section 4658.0815. As amended, it reads as follows:

Subpart 1. Responsibility of nursing home. A nursing home must ensure that all employees, prior to employment and as otherwise indicated in this part, show freedom from active tuberculosis according to this part. A nursing home must establish a tuberculosis counseling, screening, and prevention program for all

employees, in accordance with section II.J. of the "Guidelines for Preventing the Transmission of Mycrobacterium Tuberculosis in Health-Care Facilities, 1994", issued by the Centers for Disease Control and Prevention, October 28, 1994. This guideline is incorporated by reference. It is available through the Minitex library loan system. It is not subject to frequent change.

Subp. 2. Tuberculin test. All employees, unless certified in writing by a physician to have had a positive reaction or other medical contraindication to a standard intradermal tuberculin test must have a [sic] intradermal tuberculin test with purified protein derivative (Mantoux) within three months prior to employment.

Subp. 3. Written documentation of compliance. Reports or copies of reports of the tuberculin test or chest x-ray must be maintained by the nursing home.

Subp. 4. Evaluation of Symptoms. All employees exhibiting symptoms consistent with tuberculosis must be evaluated within 72 hours.

Like Part 4658.0810, it is concluded that the amendments made to this rule are necessary and reasonable and that those amendments do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.1300. Medications and Pharmacy Services; Definitions.

124. Subp. 3. Pharmacy services. This rule defines the words "pharmacy services" as "services to ensure the accurate acquiring, receiving, dispensing, and administering of all drugs to meet the needs of each resident." A number of language changes were proposed by interested persons. Among other things, it was suggested that the rule include drug reviews and clinical services. The rule language proposed is based on federal certification requirements and the Department rejected the language changes proposed. It did, however, decide to delete the reference to dispensing because the Department of Health does not regulate dispensing of drugs. The rule was shown to be necessary and reasonable and the amendment made does not constitute a substantial change.

Part 4658.1305. Pharmacist Service Consultation.

125. This rule requires that nursing homes employ or obtain the services of a licensed pharmacist who will provide consultation on the provision of pharmacy services, establish systems for monitoring controlled drugs, and determine the accurate maintenance of drug records. It was suggested that the rule be amended to specifically state that pharmacists must make drug reviews and must be licensed. The rule, which is based on federal certification language, doesn't require that the licensed pharmacist referred to in the rule must be the same pharmacist who performs the drug regimen review under Part 4658.1310. The Department noted, however, that the same pharmacist can perform both functions. The Department decided to clarify the rule with respect to the pharmacist's licensure. The rule, as amended, was shown to be necessary and reasonable and the clarification made does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.1310. Drug regimen Review.

126. 4658.1310, Item A. This rule requires a drug regimen review of each resident every 30 days. It states that the review must be done in accordance with Appendix N of the State Operations Manual adopted by HCFA in April 1992. A number of individuals objected to incorporating Appendix N by reference in Item A. However, the Department determined that Appendix N is appropriate because it addresses the indicators for surveyor assessment of the performance of drug regimen reviews. It noted that the indicators in Appendix N are used to discern patterns of performance by the pharmacist and to detect irregularities, among other things. The provisions of Appendix N, in the Department's view, are appropriate for the performance of drug regimen reviews in nursing homes. Under the Medicare program, skilled nursing facilities must use Appendix N. Under the Medicaid program, states have the option of using Appendix N or other survey criteria developed by the state which are, at a minimum, equal to the indicators in Appendix N. It is concluded, therefore, that incorporating Appendix N by reference is necessary and reasonable.

127. 4658.1310, Item B. This rule requires the pharmacist performing the drug regimen review to report any irregularities found to the director of nursing services and the attending physician. The rule states that the pharmacist's report must be acted on by the time of the next physician visit or sooner if indicated by the pharmacist. The physician and the director of nursing services must act on the report by either accepting or rejecting it and initialling it. Numerous and varied comments regarding the language of this rule were submitted by interested persons. Interested persons questioned the need for the physician to initial the pharmacist's report and the need to report to both the physician and the director of nursing services. They suggested a time limit when some action on the report must be taken. The Department declined to amend the rule in response to these comments. It noted that only irregularities must be reported. The Department also noted that irregularities must be reported to keep professional people informed so that appropriate action can be taken. The signing and initialing of the report is designed to provide documentation that the report was received and acted upon. The rule initially proposed by the Department was shown to be necessary and reasonable.

128. 4658.1310, Item C. If the attending physician doesn't concur with the pharmacist's recommendation, this rule requires that the matter be reported to the medical director and reviewed by the QAA committee under Part 4658.0070. The QAA committee must make a recommendation to the attending physician relating to the pharmacist's report. Among other things, interested persons suggested that it is inappropriate to report a physician's disagreement with a pharmacist to the QAA committee, that the pharmacist should be responsible for reporting disagreements to the medical director and the QAA committee, or that the provisions should be totally eliminated. In response to the many comments filed, the Department has decided to amend Item C to read as follows:

> If the attending physician does not concur with the pharmacist's recommendation or does not provide adequate justification, and the pharmacist believes the resident's quality of life is being

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

Although there are a number of ways the procedure for reviewing disagreements between the pharmacist and the doctor should be handled, the procedures proposed by the Department under the amended rule were shown to be necessary and reasonable and the amendments made to the rule do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.1315. Unnecessary Drug Usage.

129. Subpart 1. General. This rule states that a resident's drug regimen must be free from unnecessary drugs. That is, drugs used in excessive dose, for excessive duration, without adequate indication for usage, or when contraindicated. It incorporates by reference HCFA's interpretive Guidelines (Appendix P) which contain guidelines relating to drug usage. The rule was shown to be necessary and reasonable. However, the Department should consider adding the page numbers of those portions of Appendix P which are incorporated by reference here. The Department apparently intends to incorporate the interpretive guidelines which begin on P-139 and end on P-147.

130. Subp. 2. Monitoring. Under this rule, nursing homes must monitor each resident's drug regimen for unnecessary drug usage and report any irregularities to the resident's attending physician. If the physician does not concur with the nursing home's recommendation, the rule states that the matter must be reported to the medical director and reviewed by the QAA committee, which in turn must make recommendations to the physician. Interested persons stated that involving the medical director and the QAA committee based on a pharmacist's recommendation gives the pharmacist too much authority and that the QAA committee shouldn't be making recommendations to physicians regarding the practice of medicine. The Board of Pharmacy stated that the rule should be amended to require the pharmacist, in cooperation with the director of nursing services, to monitor each resident's drug regimen, and when a physician does not concur with a pharmacist's recommendation, the pharmacist should be required to report the matter to the medical director and the QAA committee. Another person questioned whether it was necessary to review every episode of physician nonagreement.

In response to public comments, the Department proposes to amend subp. 2, consistent with amendments made to Part 4658.1310, Item C. In the Department's view, pharmacists should not be the only persons involved in the monitoring of a resident's drug regimen review. As amended, subp. 2 will state:

A nursing home must monitor each resident's drug regimen for unnecessary drug usage, based on the nursing home's policies and procedures, and the pharmacist must report any irregularity to the

resident's attending physician. If the attending physician does not concur with the nursing home's recommendation, or does not provide adequate justification, and the pharmacist believes the resident's quality of life is being adversely affected, the pharmacist must refer the matter to the medical director for review if the medical director is not the attending physician. If the medical director determines that the attending physician does not have adequate justification for the order and if the attending physician does not change the order, the matter shall be referred to the Quality Assurance Assessment (QAA) committee required by Part 4658.0070 for review. If the attending physician is the medical director, the consulting pharmacist shall refer the matter directly to the QAA.

The rule, as amended, was shown to be necessary and reasonable and the changes made after initial publication do not constitute prohibited substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.1320. Medication Errors

131. 4658.1320. Item A. This rule requires nursing homes to ensure that it has medication error rates less than five percent as described in Appendix P of HCFA's surveyor Guidelines. It states that a medication error is one which involves a discrepancy between what was prescribed and what was administered and the administration of expired medications. CPM argued that the Guidelines should not be incorporated by reference. Ex. 47. John Haugen, a registered pharmacist, stated that the Department's definition of a medication error, which is more expansive than the definition in the federal Guidelines, makes the five percent test meaningless. Ex. 70. In response to these comments, and others, the Department proposes to amend Item A to read as follows:

> A. its medication error rate is less than five percent as established in the Interpretive Guidelines for Code of Federal Regulations, Title 42, section 483.25(m), found in Appendix P of the State Operations Manual, Guidance for Surveyors for Long-Term Care Facilities, incorporated in Part 4658.1315. For purposes of this part, a medication error means:
>
> (1) A discrepancy between what was prescribed and what medications were actually administered to residents in the nursing home; or
>
> (2) the administration of expired medications.

The rule, as amended, was shown to be necessary and reasonable, and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993). Although HCFA guidelines are not binding regulations, the Department can incorporate them by reference when it concludes that they contain appropriate standards for purposes of implementing its responsibilities under state law.

132. 4658.1320, Item B. Under this rule nursing homes must be free of any significant medication errors. It defines a "significant" error as one

which causes the resident discomfort or jeopardizes the resident's health or safety or medications from a category that usually requires a specific blood level when the error could alter the titrated blood level of the medication and cause a reoccurrence of symptoms or toxicity. Interested persons stated that the language in Item B is ambiguous, incomplete, and inconsistent with HCFA guidelines. The rule was shown to be necessary and reasonable as proposed. It follows the language of federal guidelines except with respect to the frequency of medication errors. The Department determined not to consider frequency because even one- time medication errors can be significant.

133. 4658.1320, Item C. This rule requires that medications must be administered as prescribed. When a medication error occurs, an incident report or medication error report must be filed. Any significant medication error or resident reaction must be reported to the physician and the resident's legal designee and an explanation included in the resident's clinical record. David E. Holmstrom, Executive Director of the Minnesota Board of Pharmacy suggested that Item C be amended to require nursing homes to report medication errors to the consulting pharmacist. Ex. 53. Dean R. Schmidt, a registered pharmacist, stated that medication errors should only be reported to the resident's legal designee if they result in significant adverse consequences to the resident. In other cases, he stated that reporting medication errors might cause unnecessary alarm to the resident's family. Ex. 36. The Department determined, however, that significant medication errors should be reported to the resident's guardian or chosen representative. That is a necessary and reasonable policy decision. The rule, as amended by the Department, was shown to be necessary and reasonable and the amendments made are not substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.0325. Administration of Medications.

134. Subp. 6. Medications added to food. This rule states that any medications added to a resident's food must be prescribed by the resident's physician and the resident must consent. Interested persons objected to the rule insofar as it requires a physician order or resident consent when a medication is mixed with applesauce, for example, simply to make it easier to swallow. They also suggested that they should be able to obtain consent from the resident's guardian or legal representative when the resident is incompetent. In response to these comments, has decided to amend subp. 6 to make it clear that the resident or the resident's guardian or chosen representative must consent to have a medication added to food and to exempt the practice of adding medication to food for the sole purpose of a resident's ease in swallowing. The rule, as amended, was shown to be necessary and reasonable. The amendments do not constitute substantial changes.

135. Subp. 8. Documentation of administration. As originally proposed, this rule required that the name, date, time, quantity of dosage, and method of administration of all medications must be recorded in the resident's clinical record. Among other things, interested persons questions whether administration must be followed by documentation. In response to public comments, the Department proposes to amend subp. 8 to read as follows:

> Subp. 8. Documentation of administration. The name, date, time, quantity of dosage, and method of administration of all medications,

and the signature of the nurse or authorized persons who administered and observed the same must be recorded in the resident's clinical record. Documentation of the administration must take place following the administration of the medication. If administration of the medication was not completed as prescribed, the documentation must include the reason the administration was not completed, and the follow-up that was provided, such as notification of a registered nurse or the resident's attending physician.

The rule, as amended, was shown to be necessary and reasonable, and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

Part 4658.1335. Drugs In Stock.

136. Subpart 1. Stock supply drugs. This rule states that only "medications obtainable without prescription may be retained in stock supply and must be kept in the original container." Two person questions the rule because it would not allow stock PPD (purified protein derivative) to be available without prescription. The Department refused to amend the rule to allow PPD to be available without prescription. The rule, which is consistent with current requirements in 4655.7720, is authorized and its need and reasonable need not be reestablished in this proceeding. The Department did revise the language in subp. 1, however, to clarify its meaning. The changes made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

137. Subp. 2. Emergency drug supply. This rule states that a nursing home must have emergency drug supply approved by the QAA committee for use when necessary for resident care and emergencies. It states that the contents, maintenance, and usage of the emergency supply must comply with Part 6800.6700 adopted by the Board of Pharmacy. The Department refused to amend the rule so that the medical director could approve the contents of the emergency kit. It did, however, propose clarifying amendments to the rule as suggested by Mr. Haugen. The rule, as amended, was shown to be necessary and reasonable and the amendments made do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1993).

138. Subp. 3. Prohibitions. This rule states that a prescription drug supply for one resident cannot be used or saved for the use of another resident and that the QAA committee must monitor for the use of borrowed medications. Based on public comments received, the Department is amending the rule to eliminate the QAA committee's responsibility to monitor the use of borrowed medications. The rule, as amended, was shown to be necessary and reasonable and not to involve a substantial change.

Part 4658.1350. Disposition of Medications.

139. Subpart 1, Item A. This rule states that a resident's medications must be returned to the resident upon transfer or discharge and then recorded on the clinical record. In response to public comments, the Department proposes to amend Item A to read as follows:

> Current medications, except controlled substances listed in Minnesota Statutes, section 152.02, subdivision 3, belonging to residents must be given to the resident or the resident's guardian or chosen representative when discharged or transferred and must be recorded on the clinical record.

The rule, as amended, is responsive to public comments and is necessary and reasonable.

140. Subp. 1, Item B. This rule relates to the disposition of controlled substances remaining in the nursing home after a resident's death or discharge. In response to public comments, the Department proposes to make Item B part of a new subpart which will read as follows:

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

The rule, as amended, was shown to be necessary and reasonable and the changes made are not substantial.

141. Subp. 1, Item C. This rule relates to the disposition of prescription drugs other than controlled substances after the death or discharge of a resident for whom they were prescribed as well as any prescriptions permanently discontinued. Interested persons suggested that the rule be amended to address unit dose medications returned to the pharmacy for credit and authorize pharmacists as well as registered nurses to destroy them. In response to these comments, the Department purposes to change Item C to a new Item B, to authorize a pharmacist or a registered nurse in the presence of one other nursing staff person to destroy medications and to require the signature of the pharmacist or registered nurse and witness involved in the destruction on the clinical record. The rule, as amended, was shown to be necessary and reasonable and does not involve a substantial change. Although the Department did not amend the rule to specifically deal with unit dose medications, that issue is adequately addressed in subpart 3 of the rules.

Part 4658.1360. Administration of Medications by Unlicensed Personnel.

142. Subpart 1. Training. This rule requires that unlicensed nursing personnel who administer medications must have completed a nursing assistant training program approved by the Department, and a standardized medication administrative training program at a post-secondary educational institution which includes instruction on the complete procedure of checking the resident's record, transferring individual doses from the resident's prescription container, distribution to the resident, and documentation. The

Department made a number of changes in subp. 1 as suggested by interested persons. The rule, as amended, was shown to be necessary and reasonable and none of the language changes made constitute a substantial change in the rule. The Department refused to revise the language of Item B to replace the word "standardized" with the words "which meets standards established by the Minnesota Board of Nursing." It also refused to add language from the Board of Nursing rules to the nursing home licensing rules. None of those changes are legally required, and the Department decision not to adopt them does not affect the need and reasonableness of the rule.

143. Subp. 3. Medical administration. This rule states that a person who completes the required training course can administer regularly scheduled medications. In the case of pro re nata (PRN) medication, administration must be reported to a registered nurse prior to administration. The Department made minor, clarifying changes to the substance of the rule in response to public comments. The rule, as amended, was shown to be necessary and reasonable and not involve a substantial change.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. That the Minnesota Department of Health (Department) gave proper notice of the hearing in this matter.

2. That the Department has fulfilled the procedural requirements of Minn. Stat. §§ 14.14, and all other procedural requirements of law or rule.

3. That the Department has documented its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i) and (ii).

4. That the Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii).

5. That the additions and amendments to the proposed rules which were suggested by the Department after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, Minn. Rule 1400.1000, Subp. 1 and 1400.1100.

6. That any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

7. That a finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED: that the proposed rules be adopted consistent with the Findings and Conclusions made above.

Dated this 15th day of February, 1995.

JON L. LUNDE
Administrative Law Judge