Minnesota Department of Health
Health Resources Division
393 North Dunlap
P.O. Box 64900
St. Paul, MN 55164-0900
(612) 643-2100

OCT 13 1994

October 12, 1994

Ms. Maryanne V. Hruby, Executive Director
Legislative Commission to Review Administrative Rules
55 State Office Building
100 Constitution Avenue
St. Paul, Minnesota 55155

Re: In the Matter of Proposed Rules of the State Department of Health Relating to Licensing, Administration, and Health Services in Licensed Nursing Homes

Dear Ms. Hruby:

The Minnesota Department of Health intends to propose rules relating to licensing, administration, and health services in licensed nursing homes. We plan to publish a Notice Of Proposed Permanent Rules in the October 17, 1994 State Register.

As required by Minnesota Statutes, sections 14.131 and 14.23, the Department has prepared a Statement of Need and Reasonableness which is now available to the public. Also as required, a copy of this Statement is enclosed with this letter.

For your information, we are also enclosing a copy of the Notice Of Proposed Permanent Rules and a copy of the proposed Rules in this matter.

If you have any questions about these rules, please contact me at 612/643-3615.

Sincerely,

Maggie Friend
Rules Coordinator

enclosures:
Notice Of Proposed Permanent Rules
Proposed Rules
Statement of Need and Reasonableness

To be published in the October 17, 1994 *State Register*:

DEPARTMENT OF HEALTH

PROPOSED PERMANENT RULES RELATING TO LICENSING, ADMINISTRATION, AND HEALTH SERVICES IN LICENSED NURSING HOMES AND PROPOSED AMENDMENTS OF PERMANENT RULES RELATING TO THE PHYSICAL PLANT OF LICENSED NURSING HOMES, FINING SCHEDULES FOR NONCOMPLIANCE WITH CORRECTION ORDERS, RESIDENT SERVICES IN VETERANS HOMES, AND MEDICAL ASSISTANCE PROGRAM DEFINITIONS.

NOTICE OF HEARING

NOTICE IS HEREBY GIVEN that a public hearing on the above-entitled matter will be held in the Capitol Room, Capitol View Conference Center, 70 West County Road B2, Little Canada, Minnesota, beginning at 9:00 a.m. on Monday, November 21, 1994, and continuing until all interested or affected persons have an opportunity to participate. The hearing will continue, if necessary, at additional times and places as determined during the hearing by the administrative law judge.

Hearing procedures. Following the agency's presentation at the hearing, all interested or affected persons will have an opportunity to participate. Such persons may present their views either orally at the hearing or in writing at any time prior to the close of the hearing record. All evidence presented should be pertinent to the matter at hand. Written material not submitted at the time of the hearing which is to be included in the hearing record may be mailed to Jon L. Lunde, Administrative Law Judge, Office of Administrative Hearings, 100 Washington Square, Suite 1700, Minneapolis, Minnesota 55401-2138; telephone 612/341-7645, either before the hearing or within five working days after the public hearing ends. The Administrative Law Judge may, at the hearing, order the record be kept open for a longer period not to exceed 20 calendar days. Any written material or responses must be received at the office no later than 4:30 p.m. on the final day. The comments received during the comment period shall be available for review at the Office of Administrative Hearings.

Following the close of the comment period the agency and all interested persons have five business days to respond in writing to any new information submitted during the comment period. During the five-day period, the agency may indicate in writing whether there are any amendments suggested by other persons which the agency is willing to adopt. No additional evidence may be submitted during the five-day period. Any written material or responses must be received at the office no later than 4:30 p.m. on the final day. The written responses shall be added to the rulemaking record. Upon the close of the record the Administrative Law Judge will write a report as provided for in *Minnesota Statutes*, section 14.50. The rule hearing is governed by *Minnesota Statutes*, section 14.14 to 14.20 and by *Minnesota Rules*, parts 1400.0200 to 1400.1200. Questions about procedure may be directed to the Administrative Law Judge.

Subject of Rule and Statutory Authority. The Department of Health intends to adopt a

permanent rule after a public hearing following the procedures set for in the Administrative Procedure Act, *Minnesota Statutes*, sections 14.22 to 14.28. Currently, licensed nursing homes and boarding care homes are subject to Minnesota Rules Chapters 4655 and 4660. These proposed rules would supersede portions of those current rules. The text of the proposed rules and amendments follows this notice.

Minnesota Rules, parts 4658.0010 to 4658.0580 and 4658.0700 to 4658.1365 (Proposed) address licensing, administration, restraints, comprehensive resident assessments and plans of care, clinical records, nursing services, medical and dental services, infection control, and medications and pharmacy services to be provided in licensed nursing homes. **Minnesota Rules**, parts 4655.9200 to 4655.9400 address the fining schedule for noncompliance with correction orders relating to violations of Chapters 4655 and 4660. *Minnesota Rules*, parts 4660.1700 and 4660.5030 address the physical plant and equipment requirements for the medication room and laundry equipment, respectively, in licensed nursing homes. Citations to nursing home operations rules have been revised to reference the proposed rules. *Minnesota Rules*, parts 9050.0040, 9050.0210, 9050.1030, and 9050.1070 address resident services provided to residents in facilities owned or operated by the Minnesota Veterans Homes Board. Citations to nursing home operations rules have been revised to reference the proposed rules. *Minnesota Rules*, part 9505.0390, provides definitions for rehabilitative and therapeutic services in the medical assistance program. A citation to a nursing home operations rule has been revised to reference the proposed rule.

The statutory authority to adopt the rule is *Minnesota Statutes*, sections 144A.04, subdivision 3 and 144A.08, with the revisions developed under the authority of *Minnesota Laws* 1991, Chapter 292, Article 4, Section 55.

Comments. Written comments in support of or opposition to the proposed rule or any part or subpart of the rule must be in writing and received by the Administrative Law Judge by the due date. Comment is encouraged. Your comments should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Agency Contact Person. Copies of the proposed rules are available and may be obtained by writing or calling the agency contact person. Comments or questions on the rule must be submitted to:

Maggie Friend
Minnesota Department of Health
Facility and Provider Compliance Division
393 North Dunlap Street
P.O. Box 64900
St. Paul, Minnesota 55164-0900
Telephone: (612) 643-3615
Fax: (612) 643-2593

Modifications. The proposed rule may be modified, either as a result of public comment or as a result of the rule hearing process. Modifications must not result in a substantial change in the proposed rule as attached and printed in the *State Register* and must be supported by data and

views submitted to the administrative law judge or presented at the hearing. If the proposed rule affects you in any way, you are encouraged to participate in the rulemaking process.

Statement of Need and Reasonableness. Notice is hereby given that a statement of need and reasonableness is now available for review at the agency and at the Office of Administrative Hearings, or may be obtained from the agency contact person. This statement describes the need for and reasonableness of each provision of the proposed rule. It also includes a summary of all the evidence and argument which the agency anticipates presenting at the hearing. The statement may also be reviewed and copies obtained at the cost of reproduction from the Office of Administrative Hearings.

Statement of Anticipated Costs and Benefits. *Minnesota Statutes*, section 144A.29, subdivision 4 (1993) requires each rule promulgated by the commissioner of health pursuant to sections 144A.01 to 144A.15 to contain a short statement of the anticipated costs and benefits to be derived from the provisions of this rule. This statement has been prepared and is available from the agency contact person.

Small Business Considerations. In preparing these rules, the Department of Health has considered the requirements of *Minnesota Statutes*, section 14.115, in regard to the impact of the proposed rules on small businesses. Subdivision 7 of that section exempts rules that affect "service business regulated by government bodies, for standards and costs, such as nursing homes, long-term care facilities, hospitals, providers of medical care, day care centers, group homes, and residential care facilities...." It is the Department's position that this rule is exempt from §14.115, because nursing homes are specifically exempted in that statute.

Expenditure of Public Money by Local Public Bodies. The implementation of this rule will not have a total cost of over $100,000 to local public bodies in either of the two years immediately following the adoption of the rule.

Impact on Agricultural Lands. This rule will not pose any direct adverse impacts on agricultural land as specified in *Minnesota Statutes*, section 17.80 to 17.84.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A requires each lobbyist to register with the Ethical Practices Board. Questions regarding this requirement may be directed to the Ethical Practices Board at First Floor Centennial Office Building, 658 Cedar Street, St. Paul, Minnesota 55155, (612) 296-5148.

Departmental Charges. *Minnesota Statutes*, section 16A.1285, subdivisions 4 and 5, do not apply because the rules do not establish or adjust departmental charges. Although portions of the rules relate to the schedule of fines for nursing home violations, the Department believes that the fines are exempt from the procedures of Minnesota Statutes section 16A.1285, subdivisions 4 and 5 because the fines are nonrecurring and do not produce significant revenues.

Adoption Procedure After the Hearing. After the close of the hearing record, the administrative law judge will issue a report on the proposed rule.

Notice: You may request to be notified of the date on which the administrative law judge's report will be available, after which date the agency may not take any final action on the rule for a period of five working days. If you want to be notified about the report, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the administrative law judge. You may also request notification of the date on which the rules are adopted and filed with the secretary of state. The agency's notice of adoption must be mailed on the same day that the rules are filed. If you want to be notified of the adoption, you may so indicated at the hearing or send a request in writing to the agency contact person at any time prior to the filing of the rule with the secretary of state.

Dated 10/4/94

Mary Jo O'Brien, Commissioner
Minnesota Department of Health

Rules as Proposed

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Department of Health concerning Licensing, Administration, and Health Services in Licensed Nursing Homes, Minnesota Rules, Chapter 4658

STATEMENT OF NEED AND REASONABLENESS

September 13, 1994

Minnesota Department of Health
Health Resources Division
393 North Dunlap Street, P.O. Box 64900
Saint Paul, Minnesota 55164-0900

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BACKGROUND AND LEGAL AUTHORITY

The proposed Minnesota Rules, parts 4658.0010 through 4658.1365, establish standards for the use of licensing, waivers and variances, administration, restraints, comprehensive resident assessment, comprehensive plan of care, clinical records, nursing services, medical director, physician services, dental services, infection control, and medications and pharmacy services in licensed nursing homes. These proposed rules set forth requirements considered necessary to ensure the health, safety, well-being and appropriate treatment of persons residing in nursing homes. The rules implement Minnesota Statutes, §§144A.02 to 144A.18, under the authority of Minnesota Statutes, §144A.04, subdivision 3, and §144A.08, with the revisions developed under the authority of Minnesota Laws 1991, Chapter 292, Article 4, Section 55. This Statement of Need and Reasonableness is prepared to comply with the requirements of the Administrative Procedures Act, specifically, Minnesota Statutes, §§14.131 and 14.23.

RULEMAKING PROCESS

The 1991 Minnesota Legislature added a section to law authorizing a comprehensive review of the nursing home licensure laws and regulations. This review was necessary to establish an effective regulatory program in the state. The statute added reads:

> *Sec. 55. [REGULATORY REVIEW.]*
> *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 and state enforcement systems;*
> *(2) the effectiveness of existing enforcement tools;*
> *(3) the appropriateness of current licensure standards; and*
> *(4) alternative mechanisms for dispute resolution.*

In addition to adding this section to the laws, the 1991 Legislature also passed a two-year budget increase for the Minnesota Department of Health to conduct this review and revision of the state regulations. This budget increase was funded through a surcharge on licensed nursing home and boarding care home beds. The Nursing Home Regulatory Reform Project, as the study authorized by the statute is known, was expected to take several years to complete because of the complexity of the regulations and their interrelations with resident rights and consumer expectations and with reimbursement to these long term care facilities. The project encompasses a review of all of Minnesota Rules Chapters 4655 and 4660, and portions of Minnesota Statutes Chapter 144A.

A "Notice of Solicitation of Outside Information or Opinions regarding Proposed Revision of Adopted Rules Governing the Operation of Nursing Homes and Boarding Care Homes and the Physical Plant Requirements of Nursing Homes and Boarding Care Homes as Conditions of Licensure" was published in the *State Register*, 16 S.R. 1230, on November 18, 1991. The purpose of this notice was to inform interested parties that the Minnesota Department of Health was beginning the rulemaking process and to request information and opinions from them concerning the regulation of nursing homes and boarding care homes.

INTERACTION OF FEDERAL AND STATE REGULATIONS

The purpose of the review of the existing state licensure requirements for nursing homes and boarding care homes was to assess the appropriateness of the current state regulatory system, to examine interrelationships between federal and state regulatory systems, and to determine what areas needed to be addressed under the state licensure system. Expected results included the deletion of certain current state regulations or laws, as well as additions or supplements to state regulations or laws.

Under the provisions of Minnesota law, nursing homes and boarding care homes must be licensed. The purpose of the licensure law is to assure that the services provided in these facilities meet minimum standards to protect the health, safety, comfort and well being of the facility's residents. The licensure law establishes general conditions relating to the operation and administration of these facilities, authorizes the development of regulations, and requires the inspection of these facilities by the Minnesota Department of Health. Minnesota has traditionally had very strong nursing home licensure standards in comparison to federal certification requirements and many other states' licensure standards.

Licensed nursing homes and boarding care homes wishing to participate in the federal Medicare or Medicaid programs must comply with the federal regulations known as "Requirements for Participation." Nursing homes and boarding care homes are "certified" for participation in the Medicare or Medicaid programs when they are found, through onsite surveys, to be in compliance with the federal Requirements for Participation. The majority of nursing homes in Minnesota are certified to participate in one or both of those federal programs.

In December 1987, the federal Nursing Home Reform Act was signed into law. Since this act was included in the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203), it is often referred to as "OBRA 87". The majority of the nursing home reform provisions of OBRA 87 became effective on October 1, 1990. The purpose of these provisions was to improve the quality of life and quality of care of residents in certified nursing facilities, as well as to clarify and strengthen residents' rights. These provisions marked a radical shift in the focus of federal regulations from the capacity or capability of the facility to provide appropriate services to actual facility performance in meeting residents' needs in a safe and healthful environment. There is much greater latitude for resident involvement in the care they receive due to the expanded resident notice provisions and other resident empowerment features of OBRA 87.

With the enactment of the extensive OBRA 87 provisions and the development and issuance of their implementing regulations, it was appropriate to establish a process to review Minnesota's licensure standards for areas of overlap or conflict with the new federal regulations. Since the federal regulations are more stringent than they previously were and now have a greater outcome orientation, it was thought that it may not be necessary nor appropriate for state licensure regulations to be as extensive as they have been. Rather, it might be more appropriate to use the federal certification regulations as the basic model, and modify the state licensure regulations to supplement the federal requirements in the areas deemed by Minnesotans to warrant more stringent stipulations for licensed nursing homes and boarding care homes and the services they provide.

At the same time as these federal requirements are changing, the practice and provision of long term care services are in a state of change. Alternative services are being developed that meet individual needs outside of institutions, nursing home providers are becoming more creative in services they provide in existing physical environments, and specialized service units in nursing homes are being developed or are evolving because of the changing needs of the population being served by those nursing homes. Over the years, resident and family involvement in the care and treatment received in nursing homes has occurred to varying extent. The new OBRA regulations greatly expand the potential and the necessity for that involvement, and that resident empowerment needs to be taken into greater account in our state regulations. Ideally, the regulatory process would respond to those innovations in services and settings in an effective and efficient manner, while continuing to protect the residents.

The goal, then, of this 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. These proposed changes would result in the integration of the state and federal survey processes to a far greater extent than is presently possible.

PUBLIC AND GOVERNMENTAL VIEWPOINTS

In order to gather public comment and initiate public debate on what type of licensing rules Minnesota should have for its nursing homes, a variety of methods were used to receive comments from the public and from governmental agencies.

Articles describing the regulatory review process and its status have been published regularly in *The Resource*, the quarterly publication of the MDH Health Resources Division. Also, the major provider organizations and many professional organizations have had articles on the regulatory review in their newsletters.

Interviews have been conducted with representatives of groups from whom comments were indispensable. Such groups include legislators, residents and their families, professional organizations, other state and federal officials, and national experts.

In March 1992 a survey was sent to each Minnesota nursing home and boarding care home, addressed to the Resident Councils and Family Councils. This survey attempted to gather information about resident rights, needs, safety, and other issues. 142 Resident Council questionnaires were returned, and 131 Family Council questionnaires were returned. The results of the survey were incorporated into workgroup discussions and summaries.

Public meetings have been conducted at various points throughout the process to ensure that all possible viewpoints are being received. These included approximately 20 meetings with resident and family councils at locations around the state, mainly during calendar year 1992. Many presentations have been given at meetings of professional organizations and nursing home provider associations.

Meetings with legislators or their staff were held to receive their comments and to provide updates on the project. In addition, annual reports to the Legislature on the status of the project have been published and are available to interested persons upon request.

In addition, many of the subject areas required consultation with other divisions of the Department of Health or with other state agencies that have regulations which interact with these nursing home and boarding care home licensure regulations.

REGULATORY REVIEW PROCESS

A project Steering Committee, consisting of 15 members from the public and private sectors, provides oversight to the Department on the regulatory reform process. This Steering Committee began meeting in December 1991. The charge given to the Steering Committee by the Commissioner of Health was to provide policy direction to the Department on the regulatory reform process, the examination of individual issues within that process, and the review of public comments and workgroup recommendations on proposed regulatory changes. The Steering Committee examined the regulatory areas to identify where outcome based regulations would be appropriate and provided guidance to the workgroups on the development of outcome based regulations. The Steering Committee has provided recommendations to the Department on the feasibility and extent of the integration of federal and state regulations.

The members of this Steering Committee have been:
"Greenie" Greenseth, nursing home resident
Judy Liffengren, family member
Sharon Zoesch, State LTC Ombudsman, Minnesota Board on Aging
(replacing Jim Varpness)
Iris Freeman, Minnesota Alliance for Health Care Consumers
Bonnie Peterson, Minnesota Nurses Association
Dr. Robert Meiches, Minnesota Nursing Home Medical Directors Association
(replacing Dr. Tom Altemeier)
Dr. Robert Kane, Minnesota Chair in LTC and Aging, University of Minnesota
Darrell Shreve, Minnesota Association of Homes for the Aging
Barbara DeLaHunt, Administrator, Ebenezer Luther Field Hall
Patti Cullen, Care Providers of Minnesota
Jayne Stecker, Health Dimensions, Inc.
Gail Dekker, Long Term Care Facilities Division, Minnesota Department of Human Services
(replacing Sandra Bisgaard)
Gary Karger, Long Term Care Facilities Division, Minnesota Department of Human Services
(replacing Pamela Parker)
Liz Quam, Assistant Commissioner, Minnesota Department of Health
(replacing Andrea Mitchell Walsh)
Linda Sutherland, Director, Health Resources Division, Minnesota Department of Health

After examination of the existing regulations, the Steering Committee suggested the formation of 15 workgroups to review specific areas of those regulations. There was at least one member of the Steering Committee and one department staff person on each workgroup. This helped to ensure continuity of information flow between the Steering Committee and the workgroups, as well as focusing policy direction throughout the review process. There were some areas of regulations which were addressed by more than one workgroup, or which impacted on other areas.

The Steering Committee developed a document titled, "Guidelines for Workgroups", which outlined expectations of the workgroups' review of regulations. One of the charges contained in that document was to consider how outcomes, both clinical and resident satisfaction, could be incorporated into the regulatory system. Another of the charges was to review the documentation requirements for the specific regulations and to make recommendations on what actually needs to be documented and why. Still another charge was to address how resident choice and autonomy is accounted for and allowed at the same time there are requirements which facilities must comply with.

The Steering Committee developed a prioritization for establishment and suggested membership list for the workgroups. The members of the workgroups were chosen by the Department of Health, from the over 600 names of volunteers. The initial six workgroups addressed physician and dental services, dietary and food services, infection control, nursing services, resident rights, and physical plant. The next set of workgroups addressed medications and pharmacy services, administration and operations, activities, social services, and environmental services (laundry, housekeeping, and maintenance). The third set of workgroups dealt with rehabilitation services

and other ancillary services, medical records, and whether there is a need for regulations specifically for specialized care units. The final step of the review encompasses the enforcement process.

As mentioned earlier in this document, one of the charges of the Legislature to the Department was to "address the possibility of unifying the federal and state enforcement systems." By incorporating specific portions of the federal regulations into these proposed state rules, the Department of Health is addressing that possibility of unifying those two systems, where reasonable and necessary. The intent is not to duplicate all of the federal regulatory language, but rather to utilize those parts which are applicable and appropriate. By coordinating or matching federal and state regulatory language in sections, we are attempting to decrease confusion on pertinent regulations and to eliminate regulations which are in conflict but both of which currently apply to the situation. Of the approximately 450 licensed nursing homes in Minnesota, about 1% are not certified to participate in either the Medicare or Medicaid programs. This means that 99% are certified, and so are required to follow the federal certification requirements as well as the state licensing requirements. By coordinating these two sets of regulations, regulatory expectations should be accordingly easier to understand for consumers, providers, and regulators. This should increase the efficiency and effectiveness of the regulations - and allow for more provider time to be spent providing cares to residents rather than trying to understand the rules, and which rule might take precedence in a given situation.

The charge, then, to these workgroups was to review the current state and federal rules relating to a specific service area, and suggest revisions to those rules. Those revisions could entail editorial changes, matching the state rule language to the federal language, adding new language, deleting existing language, a combination of those changes, or whatever else would make for more appropriate rules. In addition to voicing their own opinions, the workgroup members were encouraged to solicit suggestions from other persons and to share those suggestions either verbally or in writing. The intent was not to reach consensus among workgroup members as to how the rules should look, but rather to gather as much input as possible about current situations, standards of practice, and ideals. From that input, the Steering Committee could then develop proposed revisions to the current state licensing rules which mesh as much as possible with other applicable regulations nursing homes must comply with as well as make for more efficient operations.

ADMINISTRATION AND OPERATIONS WORKGROUPS

The public Administration and Operations Workgroup met four times, on September 15, 1992, September 29, 1992, October 20, 1992, and November 16, 1992. During their review of the regulations, the workgroups used a side by side comparison of the current federal and state regulations relating to licensing, administration, and operations of nursing homes. Current research, articles, and guidelines in the field of administration and operations were submitted by workgroup members, and incorporated into discussions of what the state regulations should "look like."

The members of the public Administration and Operations Workgroup were:

Barbara DeLaHunt, Administrator, Ebenezer Luther Field Hall
Iris Freeman, Executive Director, MN Alliance for Health Care Consumers
Shirley Barnes, Associate Administrator, Walker Methodist Health Care Center
Ron Johnson, Administrator, Chris Jensen Nursing Home
Susan Shaffer, Attorney, Orbovich, Fletcher, & Lafond
Kathryn Kading, R.N., D.O.N., Augustana Home of Minneapolis
Roberta Thompson, Human Resources, Park View Care Center
Dr. Jim Pattee, Medical Director - Northridge CC
Margie Kissner, Quality Assurance, Ebenezer Luther Field Hall
Kenneth J. Conant, Jr., resident, Westwood Health Care Center
Laura Hood, Office of Ombudsman for Older Minnesotans
Catherine Lloyd, Board of Examiners for NH Administrators
Nancy Saatzer, Board of Examiners for NH Administrators
Diane Halstead, MDH - Survey and Compliance Section, Metro Office
Barb Murphy, MDH - S&C Section, Central District Office

Once the public workgroup completed their discussions of regulations, an internal workgroup reviewed the same documents, research, other regulations, the summary of those public workgroup discussions, and provided their input on the development and revision of the state licensing regulations. This internal workgroup met on January 11, 1993. The members of this internal workgroup were:

Claudia Bakken, R.N., Health Facility Evaluator, Fergus Falls Office
Rita Ronayne, R.N., Unit Supervisor, Metro Office
Judy Vierling, R.N., Assistant Section Chief

When the workgroups had finalized their responses to the outcome and format questions and completed suggestions for revisions to the regulations, those suggestions were forwarded to the Steering Committee, in the form of a summary document describing the various versions of the rule parts that the workgroups devised or suggested. The Steering Committee reviewed those suggestions on August 25, 1993. The document "Administration and Operations Regulations - Proposed Revisions To State Licensing Rules - For Public Review and Comments - 10/18/93" was then developed and circulated for public review and comments. This first draft of proposed revisions to the rules was issued on October 18, 1993. It was circulated to the members of the workgroups, the project Steering Committee, Health Resources Division management, and other interested persons. They had been asked to circulate the draft to their constituents and any other interested persons. The written comment period ran through December 1, 1993.

Once the comment period expired on the draft of proposed revisions, the comments received were compiled and provided to the Steering Committee. The Steering Committee reviewed and discussed the comments received on February 2, 1994 and April 11, 1994. Final recommendations for proposed revisions to the state nursing home licensing rules for licensing, administration, and operations were then developed, and are discussed in detail below.

MEDICAL RECORDS WORKGROUPS

The public Medical Records Workgroup met three times, on May 3, 1993, May 17, 1993, and June 10, 1993. During their review of the regulations, the workgroups used a side by side comparison of the current federal and state regulations relating to medical records, comprehensive assessments, and plans of care in nursing homes. Current research, articles, and guidelines developed by professionals in the field of health information management services were submitted by workgroup members, and incorporated into discussions of what the state regulations should "look like."

The members of the public Medical Records Workgroup were:
Patti Cullen, Care Providers of Minnesota
Jayne Stecker, RN, Health Dimensions Inc.
Charleen Prill, Beverly Enterprises
Anne Tollefson, ART, Medical Records Consultant
Julie Turnberg, RN, DON, Johnson Memorial Home
Barb Fruechtl, Medical Records, Sholom Home East
Bonnie Doering, RRA, Medical Records Consultant
Michelle Doherty, RRA, Medical Records Consultant
Peggy Harnden, Social Services Department, Wilder Residence East
Denise Billington-Just, MN Alliance for Health Care Consumers
Meribeth Arndt, MN Alliance for Health Care Consumers
Ellie Laumark, MS, RRA, Surveyor, MDH Health Resources Division, St. Paul Office
Linda Squires, RN, Surveyor, MDH Health Resources Division, Rochester Office
Marlys DeBettignies, RN, Surveyor, MDH Health Resources Division, St. Cloud Office

Once the public workgroup completed their discussions of regulations, an internal workgroup reviewed the same documents, research, other regulations, the summary of those public workgroup discussions, and provided their input on the development and revision of the state licensing regulations. This internal workgroup met on May 21, 1993. The members of this internal workgroup were:

Ellie Laumark, MS, RRA, Surveyor, MDH Health Resources Division, St. Paul Office
Carol Spencer, RN, Surveyor, MDH Health Resources Division, Marshall Office
Rita Ronayne, RN, Unit Supervisor, MDH Health Resources Division, St. Paul Office
Pat Kohls, RN, Surveyor, MDH Health Resources Division, St. Paul Office

When the workgroups had finalized their responses to the outcome and format questions and completed suggestions for revisions to the regulations, those suggestions were forwarded to the Steering Committee, in the form of a summary document describing the various versions of the rule parts that the workgroups devised or suggested. The Steering Committee reviewed those suggestions on September 13, 1993 and October 6, 1993. The document "Medical Records Regulations - Proposed Revisions for Public Review and Comments - 10/20/93" was then developed and circulated for public review and comments. This first draft of proposed revisions to the rules was issued on October 20, 1993. It was circulated to the members of the workgroups, the project Steering Committee, Health Resources Division management, and other

interested persons. The written comment period ran through December 1, 1993.

Once the comment period expired on the draft of proposed revisions, the comments received were compiled and provided to the Steering Committee. The Steering Committee reviewed and discussed the comments received on January 7, 1994. Final recommendations for proposed revisions to the state nursing home licensing rules for comprehensive assessments, plan of care, and medical records were then developed, and are discussed in detail below.

NURSING SERVICES WORKGROUPS

The public Nursing Services Workgroup met four times, on April 7, 1992, April 30, 1992, May 19, 1992, and June 11, 1992. During their review of the regulations, the workgroups used a side by side comparison of the current federal and state regulations relating to nursing services in nursing homes. Current research and articles were submitted by workgroup members, and incorporated into discussions of what the state regulations should "look like." There was much discussion on the state statutes dealing with the required number of hours of nursing personnel. Since there was no research available to justify any changes to those requirements, the Department chooses not to amend those statutes at this time.

The members of the public Nursing Services Workgroup were:

Dr. Robert Kane, University of Minnesota, Chair in LTC and Aging
Gail Dekker, DHS - LTC Mgmt Division
Charles Vandeputte, Administrator, Texas Terrace Care Center
Olive Krahl, RN, DON, Monticello-Big Lake Community NH
Doris Larkin, RN, DON, Martin Luther Manor
Joy Rickert, RN
Debbie Shuna, RN, Good Neighbor Services
Mary Donkers, RN, St. Lucas Care Center
Dixie Johnson, Family Member
Tom Pettus, MD, Medical Director, Ebenezer Caroline Center
Melanie Warwas, NA/R, Monticello-Big Lake Community NH
Sylvia Hasara, Office of Ombudsman For Older Minnesotans
Beverly Hartman, RN, Unit Supervisor, MDH Survey and Compliance Section, St. Paul
Dorothy Perry, RN, MDH Survey and Compliance Section, Saint Cloud

Once the public workgroup completed their discussions of regulations, an internal workgroup reviewed the same documents, research, other regulations, the summary of those public workgroup discussions, and provided their input on the development and revision of the state licensing regulations. This internal workgroup met on June 26, 1992, July 17, 1992, and July 29, 1992.

The members of this internal workgroup were:
Judy Vierling, RN, Assistant Program Manager, MDH Survey and Compliance Section
Mary Sontag, MDH Survey and Compliance Section, St. Paul
Judy Maccanelli, RN, MDH Survey and Compliance Section, St. Paul
Sue Jackson, Director, Office of Health Facility Complaints, MDH
Carol Moen, RN, MDH HRD, Nursing Assistant Registry
Phyllis Metzger, RN, Unit Supervisor, MDH Survey and Compliance Section, St. Paul
Elizabeth Sandt, RN, MDH Survey and Compliance Section, Mankato

When the workgroups had finalized their responses to the outcome and format questions and completed suggestions for revisions to the regulations, those suggestions were forwarded to the Steering Committee, in the form of a summary document describing the various versions of the rule parts that the workgroups devised or suggested. The Steering Committee reviewed those suggestions on December 18, 1992. The document "Nursing Services Regulations - Proposed Revisions for Public Review and Comments - 4/1/93" was then developed and circulated for public review and comments. This first draft of proposed revisions to the rules was issued on April 1, 1993. It was circulated to the members of the workgroups, the project Steering Committee, Health Resources Division management, and other interested persons. The written comment period ran through May 15, 1993.

Once the comment period expired on the draft of proposed revisions, the comments received were compiled and provided to the Steering Committee. The Steering Committee reviewed and discussed the comments received on June 11, 1993. Final recommendations for proposed revisions to the state licensing rules for nursing home nursing services were then developed, and are discussed in detail below.

PHYSICIAN AND DENTAL SERVICES WORKGROUPS

The public Physician and Dental Services Workgroup met 4 times, on March 27, 1992, April 15, 1992, May 13, 1992, and June 17, 1992. During their review of the regulations, the workgroups used a side by side comparison of the current federal and state regulations relating to medical directors, physician services, and dental services in nursing homes. Current research, articles, and guidelines developed by medical professionals were submitted by workgroup members, and incorporated into discussions of what the state regulations should "look like."

The members of the public Physician Services Workgroup were:

Jayne Stecker, Health Dimensions, Inc.
Claire Melstrom, Administrator, Twin Rivers Care Center
Diane Vaughn, RN, D.O.N., St Anthony Eldercare
Paulene Grogan, Medical Records Director, Trevilla of Robbinsdale
Neil Henry, MD, Medical Director, St Anthony Eldercare
Robert Meiches, MD, Medical Director, Ebenezer Hall
Laura Hood, Central MN Ombudsman For Older Minnesotans

Ruth Vortherms, Nurse Practitioner, MN Valley Medical Association
Helen Hyllestad, Resident, St Louis Park Plaza
Kay Jones, RN, Nurse Practitioner
Cathy Zebroski, RN
Merideth Hart, MN Alliance For Health Care Consumers
Theresa Leary, RN, MDH Survey and Compliance Section, Rochester
Vernice Berg, RN, Unit Supervisor, MDH Survey and Compliance Section, St. Cloud

The members of the internal Physician and Dental Services Workgroup were:
Bev Thornberg, RN, Unit Supervisor, MDH Survey and Compliance Section, Fergus Falls
Dawn Mitlyng, RN, MDH Survey and Compliance Section, Fergus Falls
Maria Ockenfels, RN, MDH Survey and Compliance Section, St. Paul
Nora Beall, MDH Survey and Compliance Section, St. Paul
Christina Baltes, RN, MDH Survey and Compliance Section, Bemidji

When the workgroups had finalized their responses to the outcome and format questions and completed suggestions for revisions to the regulations, those suggestions were forwarded to the Steering Committee, in the form of a summary document describing the various versions of the rule parts that the workgroups devised or suggested. The Steering Committee reviewed those suggestions on January 8, 1993. Additional revisions were recommended; the workgroup developed another draft of proposed rule language. The Steering Committee revisited this issue on March 26, 1993. The document "Physician Services Regulations - Proposed Revisions for Public Review and Comments - 3/31/93" was then developed and circulated for public review and comments. This draft of proposed revisions to the rules was issued on March 31, 1993. It was circulated to the members of the workgroups, the project Steering Committee, Health Resources Division management, and other interested persons. The written comment period ran through May 12, 1993.

Once the comment period expired on the draft of proposed revisions, the comments received were compiled and provided to the Steering Committee. The Steering Committee reviewed and discussed the comments received on June 25, 1993. Final recommendations for proposed revisions to the state nursing home licensing rules were then developed, and are discussed in detail below.

Since there were no dental providers on the original public workgroup, another workgroup was formed consisting of dental providers and any interested persons from the Physician and Dental Services Workgroup. Members of this workgroup have been active in promoting national standards for providing dental services to nursing home residents, as well as writing articles and teaching classes on nursing home dental care, and so provided valuable input and language to this project. Members of this workgroup were:

Dr. Richard Hastreiter, MN Department of Health
Dr. Michael Helgeson, Appletree Dental
Dr. Steven Shuman, U of M School of Dentistry, Division of Health Ecology
Barb Smith, U of M School of Dentistry, Division of Health Ecology
Dr. John Ofstehage, VA Medical Center

Dr. Barbara Ritchie
Laura Hood, Central MN Ombudsman For Older Minnesotans
Helen Hyllestad, Resident, St Louis Park Plaza

The Dental Services Workgroup met three times: on August 25, 1992, September 22, 1992, and December 15, 1992. In addition, workgroup members conferred between these meetings and provided proposed revisions to the workgroup at the regularly scheduled meetings. The Steering Committee reviewed the workgroup's suggested language on January 8, 1993; revisions were discussed and another draft was developed. These final revisions were approved at the March 26, 1993 Steering Committee meeting. The document, "Dental Services Regulations - Proposed Revisions for Public Review and Comments - 3/29/93" was developed and circulated for public review and comments. It was circulated to the members of the workgroups, the project Steering Committee, Health Resources Division management, and other interested persons. The written comment period ran through May 7, 1993.

Once the comment period expired on the draft of proposed revisions, the comments received were compiled and provided to the Steering Committee. The Steering Committee reviewed and discussed the comments received on June 25, 1993. Final recommendations for proposed revisions to the state nursing home licensing rules were then developed, and are discussed in detail below.

MEDICATIONS AND PHARMACY SERVICES WORKGROUPS

The public Medications and Pharmacy Services Workgroup met three times, on September 2, 1992, September 28, 1992, and October 19, 1992. During their review of the regulations, the workgroups used a side by side comparison of the current federal and state regulations relating to medications and pharmacy services in nursing homes. Current research and articles were submitted by workgroup members, and incorporated into discussions of what the state regulations should "look like." The Minnesota Nurses Association submitted a position statement on medication administration by unlicensed personnel. The Minnesota Board of Pharmacy was in the process of adopting rules during the course of this project. There was a lot of comparison and discussion of those proposed rules, as well as correlation with them once they were adopted.

The members of the public Medications and Pharmacy Services Workgroup were:

Jim Varpness, Minnesota Board on Aging
Bonnie Peterson, RN, DON, Wilder Health Care Center
Mary Jane Thompson, RN, Administrator, Northridge Care Center
Fran Fronczak, RN, DON, Texas Terrace Convalescent Center
Rich Januszewski, Rph, Health Care Consultants of Minnesota
John Haugen, Rph, Capitol Medical Supply
Connie Ball, RN, Minnesota Veterans Home
Carol Watnemo, RN, Director of Consulting Services, Pharmacy Corporation of America
Marlene Aylor, family member

Dave Holmstrom, Director, MN Board of Pharmacy
Jane Brink, Office of Ombudsman for Older Minnesotans
Ione Sater, family member
Dr. Robert Sonntag, Park Nicollet Carlson
Peg Smythe, RN, MDH Survey and Compliance Section, St. Paul
Linda Squires, RN, MDH Survey and Compliance Section, Rochester

Once the public workgroup completed their discussions of regulations, an internal workgroup reviewed the same documents, research, other regulations, the summary of those public workgroup discussions, and provided their input on the development and revision of the state licensing regulations. This internal workgroup met on January 22, 1993 and February 8, 1993. The members of this internal workgroup were:

Judy Vierling, RN, Assistant Program Manager, MDH Survey and Compliance Section
Marlene Moe, RN, MDH Survey and Compliance Section, Marshall
Carol Spencer, RN, MDH Survey and Compliance Section, Marshall
Beverly Hartman, RN, Unit Supervisor, MDH Survey and Compliance Section, St. Paul

When the workgroups had finalized their responses to the outcome and format questions and completed suggestions for revisions to the regulations, those suggestions were forwarded to the Steering Committee, in the form of a summary document describing the various versions of the rule parts that the workgroups devised or suggested. The Steering Committee reviewed those suggestions on August 11, 1993 and October 20, 1993. The document "Medication / Pharmacy Services - Proposed Revisions to State Licensing Rules for Nursing Homes for Public Review and Comments - 10/27/93" was then developed and circulated for public review and comments. This first draft of proposed revisions to the rules was issued on October 27, 1993. It was circulated to the members of the workgroups, the project Steering Committee, Health Resources Division management, and other interested persons. The written comment period ran through December 13, 1993.

Once the comment period expired on the draft of proposed revisions, the comments received were compiled and provided to the Steering Committee. The Steering Committee reviewed and discussed the comments received on January 7, 1994. Final recommendations for proposed revisions to the state nursing home licensing rules for restraints (chemical and physical) and for medications and pharmacy services were then developed, and are discussed in detail below.

INFECTION CONTROL WORKGROUPS

The public Infection Control Workgroup met four times, on April 2, 1992, April 23, 1992, May 13, 1992, and June 9, 1992. As with the other workgroups, a side by side comparison of the current federal and state regulations relating to infection control in nursing homes was used during discussions. Current research, national standards and guidelines, and articles were

submitted by workgroup members, and incorporated into discussions of what the state regulations should "look like." Much information was provided to the workgroup from members of the Association for Practitioners in Infection Control, Inc. (APIC) in the form of their standards and guidelines. Also, information from the National Centers for Disease Control (CDC) was examined. The Minnesota Department of Health is in the process of reviewing and revising some of the rules relating to infection control (such as those dealing with tuberculosis testing); the Health Resources Division is monitoring the status of those reviews and intends to incorporate any applicable revisions into the nursing home licensing rules.

The members of the public Infection Control Workgroup were:

Bonnie Peterson, RN, DON, Wilder Residence East
Tim Samuelson, Administrator, St John's Lutheran Home
Chris Hendrickson, RN, Ebenezer Caroline Center,
Linda Homan, RN, Walker Methodist
Collette Snyder, Sholom Home East
Matthew Smorstoic, MD, Medical Director, Monticello-Big Lake Community NH
Amy Myers, NA/R, Sholom Home East
Fran Laufle, RN, Saint Paul
Connie Seltz, RN, Fergus Falls
Dr. John Degalau, MD, Department of Medicine, St. Paul Ramsey Medical Center
Renae Storbakken, RN, Bryn Mawr HCC
Bodell Anderson, RN, Supervisor, MDH Survey and Compliance Section, Mankato

Once the public workgroup completed their discussions of regulations, an internal workgroup reviewed the same documents, research, other regulations, the summary of those public workgroup discussions, and provided their input on the development and revision of the state licensing regulations. This internal workgroup met on June 22, 1992, July 13, 1992, and August 31, 1992. The members of this internal workgroup were:

Joan DeMarce, RN, Assistant Program Manager, MDH Survey and Compliance Section
Craig Hedberg, MDH Disease Prevention and Control Division, Acute Disease Epidemiology
Bev Thornberg, RN, Unit Supervisor, MDH Survey and Compliance Section, Fergus Falls
Dawn Mitlyng, RN, MDH Survey and Compliance Section, Fergus Falls
Maria Ockenfels, RN, MDH Survey and Compliance Section, St. Paul
Nora Beall, MDH Survey and Compliance Section, St. Paul
Christina Baltes, RN, MDH Survey and Compliance Section, Bemidji

When the workgroups had finalized their responses to the outcome and format questions and completed suggestions for revisions to the regulations, those suggestions were forwarded to the Steering Committee, in the form of a summary document describing the various versions of the rule parts that the workgroups devised or suggested. The Steering Committee reviewed those suggestions on December 4, 1992. Some major changes in the format and content of the proposed rules were suggested. Another meeting was held, with any interested members of the initial workgroups invited as well as additional practitioners in the field of infection control. A revised draft of proposed rules was developed.

The persons at this meeting, held on December 21, 1992, were:

Bonnie Peterson, RN, DON, Wilder Residence East
Chris Hendrickson, RN, Ebenezer Caroline Center,
Collette Snyder, RN, Sholom Home East
Diane Miller, RN, Bethesda Care Center
Michele Farber, RN, North Memorial Medical Center

The Steering Committee met and reviewed this next draft of suggestions for revisions to the infection control rules. The document "Infection Control Regulations - Proposed Revisions for Public Review and Comments - 5/10/93" was then developed and circulated for public review and comments. The draft of proposed revisions to the infection control rules was issued on May 10, 1993. It was circulated to the members of the workgroups, the project Steering Committee, Health Resources Division management, and other interested persons. The written comment period ran through June 25, 1993.

Once the comment period expired on the draft of proposed revisions, the comments received were compiled and provided to the Steering Committee. The Steering Committee reviewed and discussed the comments received on July 21, 1993. Final recommendations for proposed revisions to the state licensing rules for infection control in nursing homes were then developed. During 1993, the Commissioner of Health convened a Commissioner's Task Force on Tuberculosis. The recommendations of that task force were published in March 1994. Issues relating to transmission of tuberculosis (TB) in health-care settings are currently being addressed at the national level by the Centers for Disease Control (CDC). New guidelines for TB control in health-care settings are being finalized, and were incorporated into these draft rules. The final recommendations for nursing home licensing rules relating to infection control are discussed in detail below.

RULE PARTS

A new rule chapter, including a new numbering system, is being implemented for these rules. Some of the rule language from the current Chapter 4655 is being maintained, and incorporated in the new Chapter 4658. Due to this, a statement of need and reasonableness will be established only for material that differs from original language.

The remainder of this Statement addresses each provision of the proposed revised rule.

LICENSING

4658.0010 DEFINITIONS.

Part 4658.0010 of these proposed rules is an updating of the current rule part 4655.0100, which also lists definitions of terms used later in the rule. It is necessary and reasonable to include definitions of certain terms to allow for consistent interpretation and applicability of the rules.

The terms "ambulatory" and "patient" were not moved over to this rule chapter because they are not used in this rule. The terms "patient" and "resident" are used in Chapter 4655 to distinguish between those persons residing in nursing homes and boarding care homes, respectively. Since the proposed Chapter 4658 will only apply to nursing homes, it is not necessary to distinguish between persons residing in facilities with those differing licensure levels in this chapter.

The term "nursing assistant" was added to the list of definitions because that is a new term to these licensing rules. The definition used is based on federal certification language and on state statutory language. It is necessary and reasonable to include this definition in the rule to clarify the meaning of that term as it is used in conjunction with terms relating to other nursing personnel, and what the role of a nursing assistant may be in a licensed nursing home.

4658.0015 COMPLIANCE WITH REGULATIONS AND STANDARDS.

Part 4658.0015 is an updated version of the current part 4655.0110, and incorporates federal certification language. The proposed language has been added to strengthen the requirement and expectation that the nursing home is operated in compliance with all other applicable laws, regulations, and codes, and in accordance with professional standards of practice for the various disciplines providing services in the nursing home. It is necessary to include such a statement in these licensing rules, first to educate people that there are other applicable requirements and regulations, and second to clarify that there are standards of practice and care developed by professionals to be adhered to by persons practicing those professions. The language being added is reasonable because it corresponds directly to federal regulatory language which states that there are other regulations and professional practice standards to be followed.

4658.0020 LICENSING IN GENERAL.

Subparts 1 and 2 of the proposed part 4658.0020 contain language found in the current part 4655.0300, subparts 1 and 2.

Subpart 3 of the proposed part 4658.0020 is a revision to the current part 4655.0300, subpart 3. The current language requires that all licenses expire on December 31, annually. The proposed language would change that expiration point to correspond with the anniversary date of issuance. This change is necessary to provide a clarification to the license application process and more accurately match licensing fees to an annual licensing period. It will also provide for more efficient application processing and scheduling of work flow by the Department, by spreading the time frame for processing license renewals, as well as initial applications, over the

entire year. The language being proposed is reasonable because it takes into account the actual time period during which licenses may be applied for, rather than limiting that time period.

Subpart 4 is a revision to the current part 4655.0300, subpart 4. The public workgroups, residents, and consumer advocates agreed that it would be most appropriate to have the nursing home license posted at the main entrance to the facility so that it is readily visible to persons entering the home, as well as currently in the home. The language revision is necessary to clarify where people (the public, facility staff, and government regulators) expect to see the license posted. Requiring the license to be posted at the main entrance is reasonable because it enables ready identification of the location of the license, and for most nursing homes, will not require moving the license from its current location.

Subpart 5 contains identical language to that in the current 4655.0300, subpart 5.

4658.0025 PROCEDURES FOR LICENSING NURSING HOMES.

Subparts 1 through 13 of the proposed part 4658.0025 contain language identical to that in the current part 4655.0320, except where references to proposed rules needed to be included, and except where the statute providing for a licensing fee schedule is now referenced (rather than the rule). It is necessary and reasonable to update the language to reference the applicability of these proposed rules and the applicable statute in the procedures for licensing nursing homes. Also, a sentence was added to subpart 5, incorporating statutory intent, to clarify that any outstanding penalty assessments must be made prior to the Department's acting upon a request for relicensure when there is a transfer of interest in the ownership of the nursing home. It is necessary to incorporate that language into the licensing rule to clarify that these penalty assessments must be paid by the current owners before the Department is able to process a relicensure request in order that financial obligations of the current owners are met prior to the relicensure. The language proposed is reasonable because it clearly states the requirement in terms compatible with the licensure statutes and applicable business practices.

Subpart 14 is a revision to the current 4655.0320, subpart 14. The only change is the deletion of the current item H. It is not necessary to require an indication of compliance with provisions regarding the submission of financial statements to the Department of Human Services (DHS). Under the case mix reimbursement system, nursing homes will not receive reimbursement through the Medicaid program if they do not submit their financial statements to DHS. Since that is a substantial portion of their funding, they do comply with the DHS requirements, and it is not necessary to require that as a condition of licensure.

Subpart 15 is a revision to the current 4655.0320, subpart 15. The language currently listed in the rule identifying controlling persons has been deleted in these proposed rules, deferring to the reference to the applicable statute which defines "controlling person" for the purposes of these rules. It is unnecessary and confusing to include that definition in both the statute and the rule.

Subpart 16 is a revision to the current 4655.0320, subpart 16. It is necessary to expand the list of managerial employees to also include the administrator, directors of nursing, and medical directors in order to capture the names of all persons who may be making essential decisions

regarding the operation and provision of services in the nursing home. It is also necessary to require their previous work experience in nursing homes during the past two years, regardless of where they have worked (the current language requires "previous work experience in nursing homes located in Minnesota"), to ascertain that they have an appropriate work background to be a managerial employee in a nursing home. These revisions are reasonable because they help to ensure protection of the resident's health, safety, comfort, treatment, and well-being by requiring competent managers.

4658.0030 CAPACITY PRESCRIBED.

The proposed part 4658.0030 is a revision to the current part 4655.0500. It is necessary and reasonable to revise the second sentence to provide clarification of the intent of this part. It is necessary and reasonable to add the third sentence to correlate these licensing and operations rules with the physical plant rules, which address the minimum square footage requirements for construction of facility space based on the number of licensed beds.

4658.0035 EVALUATION.

The proposed part 4658.0035 is a revision to the current part 4655.0900. It is necessary to revise this part to provide clarification to the current language that nursing homes are subject to evaluation and approval of a change in their physical plant when they are adding services which require a physical plant change. The language being proposed is reasonable because it is a clarification of the original intent of this language.

4658.0040 VARIANCE AND WAIVER.

The proposed part 4658.0040 is a compilation of the current parts 4655.1000 through 4655.1060 addressing variances and waivers from the provisions of the rule parts of chapter 4658. The compilation of those original seven rule parts into one is intended to provide ease in location of applicable requirements for requesting variances or waivers. It is necessary to include a part on variances and waivers because it allows for an opportunity for the nursing home to request permission to meet the intent of these rules through alternative methods to those specified in the rules. The language is reasonable because it clearly states the procedures and timeframes necessary for requesting variances or waivers, and for the Department to grant or deny those. There are no changes to current rule language other than those necessary to reference the applicable proposed rule parts rather than the current rule parts.

4658.0045 PENALTIES FOR LICENSING.

One part of the reorganization of the rules for licensing nursing homes involves attaching language containing the penalties for violation of the rules to their applicable parts. In the current rules, there is a separate section of the rules which includes the penalties, or fines, for all the sections. In this proposed format, we are locating the rule parts listing the penalties at the end of each section of the rules. In other words, the penalties for noncompliance with correction orders on the licensing rule parts are located at the end of the section of rules dealing with licensing, those penalties for noncompliance with correction orders on the administration

and operations rule parts are located at the end of the section of rules dealing with administration and operations, and so on. This reorganization has been done to make the penalties for noncompliance with rule parts easier to locate for consumers, providers, and regulators.

There has been some confusion with trying to locate applicable penalties under the current setup because one may have to look in more than one rule part to find the applicable penalty assessment for different sentences or subparts within a rule part. This reorganization should remove the chances for confusion or missing applicable penalties for noncompliance with correction orders based on the nursing home licensing rules.

The statutory authority for promulgating part 4658.0045, and other parts addressing penalties, is contained in Minnesota Statutes § 144A.10, subdivision 6 (1993) which provides that:

> *"A nursing home which is issued a notice of noncompliance with a correction order shall be assessed a civil fine in accordance with a schedule of fines established by the commissioner of health before December 1, 1983. In establishing the schedule of fines, the commissioner shall consider the potential for harm presented to any resident as a result of noncompliance with each statute or rule. The fine shall be assessed for each day the facility remains in noncompliance and until a notice of correction is received by the commissioner of health in accordance with subdivision 7. No fine for a specific violation may exceed $500 per day of noncompliance."*

Thus, it should be noted that the provisions of part 4658.0045 will apply only to facilities licensed as a nursing home, and will provide for the daily accrual of fines. This subpart is necessary to implement this statutory requirement. The current system of penalty assessments for noncompliance with correction orders relates the amount of the penalty assessment to the impact on the resident resulting from noncompliance with the statute or rule. In other words, it looks at how noncompliance jeopardized the health, treatment, safety, comfort, or well-being of residents.

The current schedule of penalty assessments includes an 8 tier level of fines: $50, $100, $150, $200, $250, $300, $350, and $500. The minimum penalty assessment of $50 is assigned to those rules that do not directly jeopardize the health, safety, treatment, comfort or well-being of residents. While these rules are required minimum standards necessary to promote the proper operation of the nursing home, the potential for harm presented to residents as a result of noncompliance is not direct. This minimum fine level conforms with the legislative standard that the schedule of fines take into consideration the potential for harm to residents and, at the same time, establishes a sufficient sanction for a nursing home's failure to comply with a correction order. The underlying premise of the correction order / penalty assessment system is to assure that there is an efficient mechanism to promote compliance with the nursing home rules and to assure that the licensee operates the nursing home in accordance with the licensure laws and rules.

The $100 penalty assessment is assigned to those rules which relate, in a general nature, to the administration and management of the nursing home. While noncompliance with one of these provisions need not necessarily create a substantial risk of harm, the failure to comply has the potential for jeopardizing the health, safety, treatment, comfort, or well-being of residents.

The $150 and $200 penalty assessments are assigned to those rules that are related to the physical environment and physical plant of the facilities. The $150 penalty assessment is assigned to those rules that do not necessarily impact directly on the health and safety of residents but do impact on the comfort or well-being of residents, and the $200 penalty assessment is assigned to those rules that may impact on the health or safety of residents. This also includes the rules relating to the furnishing of resident rooms and other areas of the nursing home. The licensure rules establish minimum requirements which are necessary for the proper construction, maintenance, equipping and operation of the nursing home. The rules which have been assigned to these two assessment levels are necessary to ensure that the physical plant and physical environment are maintained in such a manner to fully protect the health, safety, treatment, comfort, or well-being of the residents. The failure to comply with the provisions of these rules will deprive residents of the minimum requirements established by the Department to assure that an adequately furnished and safe environment is provided. For that reason, noncompliance with the rules in this category will create a situation which could potentially jeopardize the health, safety, treatment, comfort, or well-being of residents.

While the rules assigned to these two fine categories relate to similar areas, the impact of noncompliance with the rules on the health, safety, treatment, comfort, or well-being of the residents does differ. Therefore, to comply with the requirement that the schedule of fines take into consideration the potential for harm, the $150 and $200 categories were developed. The $150 penalty assessment has been assigned to those rules for which noncompliance would not necessarily impact directly on the health and safety of residents but would impact on the comfort or well-being of residents.

The $200 penalty assessment has been assigned to those rules for which noncompliance could impact on the health or safety of residents in the facility. Since the potential for harm is greater than the rules contained in the $150 category, the $50 increase in the amount of the fine is appropriate. Rules which are designed to promote safety, proper sanitation, or the prevention of infection have also been included in this category. These rules relate to the environment and do have an impact on the health and safety of residents.

The $250 penalty assessment is assigned to those rules and statutes that relate to the protection of the individual rights of residents. These provisions are designed to assure that the individual rights of residents are promoted and protected in the nursing home. A violation of one of these provisions could jeopardize the well-being of residents and could also jeopardize the resident's health. The rules are necessary to assure that the residents' rights to privacy and the right to adequate and considerate care are fully protected. The $250 fine is appropriate to assure that these important interests are fully protected within the nursing home.

The $300 and $350 fine levels have been assigned to those rules which relate to the provision of care services with the nursing home. The provisions contained within these rules relate to the primary purpose of a nursing home - to provide nursing care and other services to residents. The failure to provide these services in accordance with the minimum standards contained in the rules has the potential for jeopardizing the health, safety, treatment, comfort, or well-being of residents. The importance of assuring that the mandated services are provided justifies the imposition of the $300 and $350 penalty assessments. While the rules contained in this category

all relate to the provision of care services to the residents, the impact of noncompliance on the health, safety, treatment, comfort, or well-being of residents does differ. Therefore, to comply with the requirement that the schedule of fines take into consideration the potential for harm, the two fine levels were established.

The $300 penalty assessment has been assigned to those rules that are necessary to assure that the service is properly provided, e.g. staffing, general orientation and in-service requirements, development of policies and procedures governing the provision of care, availability of equipment and supplies, etc. Noncompliance with these rules would affect the quality of care that is provided to the residents. These rules are directly related to the actual provision of the service, and compliance with these rules is necessary to assure that the actual provision of the service is done in a safe and effective manner. Noncompliance with these rules would result in the inability to adequately meet the needs of the residents and the Department believes that the $300 fine is appropriate.

The $350 penalty assessment has been assigned to those rules which relate to the direct provision of services to residents. Since the impact of noncompliance with those provisions would be more immediate, the Department believes that the additional increase of $50 is appropriate. Examples of rules contained in this category would include the provision that medications and treatments be administered in accordance with the physician's instructions, assuring that the dietary needs of residents are met and that the food is of acceptable quality and is prepared, served, and handled in a safe and sanitary manner, and assuring that staff are trained prior to providing care to residents. The direct relationship of these rules to the provision of the service in a safe manner justifies the $350 fine.

The maximum penalty assessment of $500 is assigned to those rules and statutes for which noncompliance with a correction order would present an imminent risk of harm to the health, treatment, comfort, safety, or well-being of nursing home residents. Continued noncompliance with these rules would create a substantial probability that a resident would be subjected to serious physical, mental, or psychosocial harm. A violation of the provisions assigned to this fine level justifies the maximum fine due to the potential for harm presented to the resident by noncompliance with these provisions. The maximum fine is appropriate and necessary to fully protect nursing home residents.

Penalty assessments for current rule language which has been renumbered or only editorially revised have not been changed. This includes the proposed parts 4658.0020, 4658.0025, 4658.0030, and 4658.0035. The penalty assessments for these rule parts are consistent with penalties for related topics found in other rule parts. They are reasonable because they take into consideration the potential for harm to residents while at the same time establishing sufficient sanctions to ensure compliance with applicable statutes and this rule chapter.

ADMINISTRATION AND OPERATIONS

PART 4658.0050 LICENSEE.

Subpart 1 of the proposed part 4658.0050 is a revision to the current part 4655.1200 subpart 1, which includes language based on federal certification requirements for effective and efficient management, control, and operations of the nursing home. It is necessary to include the revisions to current language to clarify the intent of this part. It is reasonable to incorporate federal language into this rule part because it clearly and concisely states the expectations of the licensee of the nursing home.

Subpart 2 contains the language currently found in the first paragraph of part 4655.1200 subpart 2. The items listed in that current rule part have been relocated to a separate subpart in these proposed rules (part 4658.0050 subpart 3).

Subpart 3, items A through E, contains the language currently found in 4655.1200, subpart 2, items A through E. The term "promptly" (currently found in part 4655.1200, subpart 2, item A) has been changed in these proposed rules to "within 14 days" to provide specificity for licensees in order that they are aware of the expected timeframe in which to notify the Department of any changes in ownership of over 10% of the interest of the nursing home. The language proposed is reasonable because it allows for a sufficient and appropriate amount of time after an applicable change in ownership to gather the necessary information and transmit that to the Department.

Item F contains language currently found in 4655.1200, subpart 2, items F and G, and elsewhere in chapter 4655. Those related current rule parts were combined into this proposed item because it is necessary to clarify that there be an adequate and competent staff, and maintenance of professional standards, in the care of the residents of the nursing home as well as in the operation of that nursing home. In other words, the nursing home needs to have sufficient staff, able to perform the functions of their job, whether that includes providing cares to the residents, other services, maintenance, and operation of the nursing home. It is reasonable to require that there be an adequate and competent staff and that professional standards are maintained in order to protect the health, safety, comfort, treatment, and well-being of the residents.

The proposed items G and H contain language currently found in 4655.1200, subpart 2, items H and I.

4658.0055 ADMINISTRATOR.

Subpart 1 contains the language currently found in part 4655.1300, subpart 1 regarding the designation of one person in immediate charge of the operation and administration of the home.

Subpart 2 has been revised from the current part 4655.1300, subpart 2, to include a reference to the statute which includes an exception to the prohibition of a nursing home administrator also serving as the director of nursing services. It is necessary and reasonable to include that reference in the rule to correlate the statutory and rule language regarding the nursing home

administrator. There was discussion about eliminating the language requiring the administrator to be "full-time." Since the corresponding statute currently requires a full-time administrator, it is necessary to retain that language in the rule. A definition of "full time" is included in the rule, stating that "full time" means no less than 40 hours worked per week. It is necessary to include this definition in the rule to make the requirement for a full time administrator enforceable, to ensure that person devotes a reasonable amount of time to the administration of that nursing home. The nursing home administrator is responsible for compliance with the statutes and rules, and it is reasonable to establish a standard for the minimum amount of time necessary to complete the responsibilities of that position.

Subpart 3 is a revision to the current part 4655.1300, subpart 3. Language in the first sentence of the current rule regarding the person left in charge of the home in the absence of the administrator has been deleted ("...physically able, competent,...") because it is not necessary to state those qualifiers in rule. The federal Americans With Disabilities Act prohibits discrimination on the basis of disability. Another sentence in this subpart requires competent supervision at all times. The important requirement is that the person left in charge be capable of acting in an emergency, which is a reasonable requirement to ensure the health, safety, and well-being of the residents.

Subpart 4 is identical to the current rule part 4655.1300, subpart 4.

4658.0060 RESPONSIBILITIES OF ADMINISTRATOR.

Item A of the proposed part 4658.0060 is identical to the current rule part 4655.1400, item A.

The current part 4655.1400, item B, numbers 1 through 6 have been revised in these proposed rules into separate items, found in the proposed 4658.0060, items B through G. It is necessary to do that separation to clarify the significance of each of the items included in the responsibilities of the administrator, and to make the rules easier to read. It is reasonable to distinguish the separate items and to update language in order to reflect current terminology and standards of practice, as well as to eliminate redundant language. For example, the proposed 4658.0060, item D is a revision to the current part 4655.1400, item B, number 2. It is not necessary to state where the nursing home must keep copies of position descriptions; it is necessary that the nursing home have written job descriptions for all positions. It is not necessary to state here that employees be familiar with their duties; that requirement is included elsewhere in the rules.

The current 4655.1400, item B, number 4 has been revised in the proposed 4658.0060, item F, to more accurately reflect procedures commonly in use for maintenance and communication of the weekly time schedule.

The proposed 4658.0060, item I, a revision to 4655.1400, item D, no longer contains the term "at least annual" in regard to employee evaluations. The federal certification language contains a requirement for at least annual evaluation of nursing assistants. However, the public workgroup providing review of the regulations felt that the frequency of evaluations is a business decision for the nursing home to make, and that is not necessary nor reasonable to include in licensing rules.

4658.0065 RESIDENT SAFETY AND DISASTER PLANNING.

The proposed part 4658.0065 is a compilation and updating of the current parts 4655.1400, item F, 4660.8550, and 4655.6500. Part of the process of revision of the nursing home licensing rules includes the relocation and uniting of related topics or requirements. This is one part where that relocation has occurred. There are arguably areas throughout the proposed rules which could be relocated to alternative sections, however, an attempt was made to logically and topically group related rule parts into fairly distinct sections.

The current part 4655.6500, dealing with a safety program, has been relocated to this area of the rules which contains the rules relating to the administration and operation of the nursing home. It is necessary to do this relocating because this is a more appropriate place for this rule part. The change is reasonable because it incorporates the intent of the current rule in a more readily accessible location.

The current part 4660.8550, addressing a resident security signal, has been relocated and revised in this proposed part. Steering Committee members felt that the outcome of ensuring resident safety, by somehow monitoring the exits to the nursing home, would be more appropriately addressed in this area of the licensing rules, rather than in the physical plant area of the rules. It is necessary to somewhere in the rules require that the exit doors to the nursing home be monitored in some way to ensure that residents do not wander away from the nursing home and to ensure that there is a system or method of maintaining security of residents within the nursing home. The proposed language in subpart 2 is reasonable because it requires the nursing home to have a method of ensuring the security of exit doors, without being specific on how that security is ensured, whether it be by an audible or other electronic monitoring system, a person standing guard, or some other system or method to ensure security.

The current part 4655.1400, item F has been renumbered as the proposed part 4658.0065, subparts 3, 4, and 5. Again, this was done to make the applicable rules easier to locate and easier to read.

4658.0070 QUALITY ASSESSMENT AND ASSURANCE COMMITTEE.

The proposed part 4658.0070 is a revision to the current part 4655.1400, item G. It is necessary to revise that part and include a rule on a quality assessment and assurance committee because this committee is essential to make improvements in facility operations to correct quality deficiencies, thus improving the care provided to residents. The language being proposed is reasonable because it maintains the intent of the current state rule language while incorporating federal certification language, which almost every licensed nursing home in Minnesota must already comply with to maintain eligibility for participation in the Medicaid and Medicare programs. One change from the federal certification language is the addition of the administrator as a member of the committee. It is necessary and reasonable to require the administrator to be a member of the quality assessment and assurance committee to ensure that any reports or recommendations of the committee will be seen by the administrator. This will provide a greater continuity of information between the quality assessment and assurance committee members and the nursing home administration, allowing for improvements in care provided to residents.

4658.0075 OUTSIDE RESOURCES.

The proposed part 4658.0075 is a revision to the current 4655.2200, and incorporates federal certification language. It is necessary to revise the current rule language to include all types of services which may be furnished to residents through the use of outside resources, because there are more than just laundry or food services being obtained from outside resources in many nursing homes. It is reasonable to revise the language because it ensures that the nursing home will have a written agreement with any outside resources it uses, and those outside resources will be required to provide services in accordance with these rules. That written agreement benefits the nursing home as well as the residents by assuring that services will be provided professionally and in compliance with the nursing home licensing rules.

4658.0080 NOTIFICATION OF BOARDS.

The proposed part 4658.0080 is new language, not specifically included in current rules. Workgroup members providing recommendations for rule revisions were strongly in favor of adding a rule part stating a process for nursing homes to follow when a licensed provider is providing inappropriate services, inadequate care, or a pattern of failure to respond to resident needs in a timely manner. The discussions on this topic originated around physician services, but expanded to include other services being provided to nursing home residents. It is necessary to include this rule part to establish a standard by which licensed providers of services to nursing home residents may be evaluated, and to educate nursing homes to contact the applicable professional board when there is substandard or inappropriate care being provided to nursing home residents. The language being proposed is reasonable because it clearly states when nursing homes are expected to contact another party which has the authority to investigate or regulate professional services.

4658.0085 NOTIFICATION OF CHANGE IN RESIDENT HEALTH STATUS.

This proposed part is a compilation of portions of the current 4655.1400, item B, which discusses the formation of general policies and procedures, of the current part 4655.6700, which addresses acute illness, serious accidents, and apparent deaths, and the federal certification language on change in resident health status. It is necessary to include this rule part to provide protection to resident health, safety, comfort, treatment, and well-being, as well as to assure protection of resident rights regarding the treatment they receive. It is reasonable to require the nursing home to develop and implement policies for contacting physicians, physician assistants, nurse practitioners, family members, and other interested persons so that those decisions do not have to be made every time there is an accident, significant change in the resident's condition, a need to alter treatment significantly, a potential transfer or discharge, and the death of a resident. Rather, these potential situations have been considered and policies for notification of essential persons have been developed ahead of time. One question that gets asked frequently by nursing homes is, if a resident is expected to die soon, and the resident dies at, for example, 3:00 a.m., must the nursing home call the physician then, or can the call wait until later in the morning? This is something that can be addressed in the nursing home's policies, and can and should be discussed with the attending physicians so their preferences are noted by the nursing home. Of course, there can always be exceptions to the policies, which should be handled on

an individual basis. Most anticipated situations, however, are appropriately addressed by policies established by the nursing home.

4658.0090 USE OF OXYGEN.

The proposed rule part 4658.0090 would replace the current parts 4655.2410 and 4655.2420. It is no longer necessary to include as great of detail in the licensing rules as currently exists regarding safe storage and use of oxygen because there are safer oxygen products than when these rules were written, and nursing home staff are either familiar with their safe storage and use or can be readily trained in the safe storage and use of oxygen. The proposed language is reasonable because it sets the responsibility on the nursing home to develop and implement policies and procedures, which the nursing home is already expected to do. The proposed language imposes no new requirements on nursing homes.

4658.0095 AVAILABILITY OF LICENSING RULES.

The proposed part 4658.0095 is a revision of the current part 4655.1800, subpart 1. In this proposed language, residents and family members are added to the persons for whom copies of these licensing regulations must be made available upon request. This revision is necessary to ensure that residents and family members are able to review the state licensing regulations for their own education and clarification of expectations of what services the nursing home may provide. The language is reasonable because it promotes consumer rights and education, and it imposes no new requirement or costs on the nursing home.

4658.0100 EMPLOYEE ORIENTATION AND IN-SERVICE EDUCATION.

The proposed part 4658.0100 is a compilation of the current parts 4655.1400, item B, 4655.1800, subpart 2, 4655.5400, 4655.6200, and 4655.6800, item D. An attempt was made here to combine the portions of the current rules which address employee training, to enable ready location of those rules rather than having them spread throughout various sections of the licensing rules. Most of the language in the proposed part 4658.0100 is the same as found in current rule. However, subpart 2, which discusses employee inservice education, more closely matches federal certification language, and requires the inservice education to ensure continuing competence, address quality concerns in the nursing home, and address special needs of residents. In other words, the inservice is to focus on the specific needs of employees and residents in each nursing home. This focus on inservice education is necessary to ensure more positive outcomes in terms of resident health and satisfaction as well as in terms of staff being trained to meet the demands of their job. The language being proposed is reasonable because, as stated above, much is based on current regulatory language, and the revisions enhance the effectiveness of employee training.

4658.0105 COMPETENCY.

This proposed rule part is a compilation of the current parts 4655.1200, items F and G, 4655.2600, and 4655.5100. It is necessary and reasonable to require direct care staff to be competent and able to perform their assigned duties in order to protect the health, safety, comfort, and well-being of residents.

4658.0110 INCIDENT AND ACCIDENT REPORTING.

The proposed part 4658.0110 is a relocation of portions of the current part 4655.3900, subpart 3.

4658.0115 WORK PERIOD.

The proposed part 4658.0115 is a revision of the current part 4655.2700. It is necessary to revise the language to clarify the intent, that staff should not routinely be working double shifts, but the Department recognizes there are certain situations which may necessitate a staff member's working of more than one shift in a row. Workgroup members provided much discussion on the detrimental effects that working double shifts can have on the employee and on the residents being cared for. Some of these detrimental effects include reduced concentration, slower response times, a lesser quality of care being provided, staff burnout, and higher employee illness and turnover rates. The language is reasonable because it takes into account humane working conditions. The definition of a "normal work period" is revised from the current language to allow for changes in the way staff scheduling can be done. The language change does not mean that a work period is no longer normally eight hours; it is intended to reflect the wide range of work shifts which can occur. There are many instances, particularly for weekend staffing, where persons routinely work 10-hour days for 3 or 4 days of the week because that is their preferred schedule. The proposed revision would allow for those alternative work schedules, within the context of applicable labor laws. Examples of "emergencies" are included in the rule language to provide guidance to providers, consumer, and regulators, on when it may be justifiable to require or allow a staff person to work more than one consecutive shift.

4658.0120 EMPLOYEE POLICIES.

The proposed part 4658.0120, subpart 1 is a revision of the current part 4655.2000, subpart 2. It is necessary to revise the language to refer to "open all doors and locks" rather than the previous "keys to all doors and locks" because there are other methods in use of opening or unlocking doors besides keys. The language is reasonable because it allows the nursing home to determine what types of locking provisions or apparatus to use, and requires simply that the person in charge has the ability to access all areas of the facility other than the business office. This does not mean necessarily that the person in charge of the home does not also have access to the business office, if the licensee or administrator allows that, but rather that access to the business office may be restricted.

The proposed 4658.0120, subparts 2 and 3 are revisions to part 4655.5100, subparts 2 and 3, in the staffing and services section of the current rules. As stated earlier, one aspect of the revision of these licensing rules is to gather and group related rules into one area or section. This rule part is another example of that grouping. The only revisions to the language in these subparts are to replace "shall" with "must", in accordance with instructions from the Office of the Revisor of Statutes, and to refer to "residents" rather than "patients and residents".

There was considerable discussion about revising subpart 3 to require "first and last name" on

the identification badges to enable complete identification of employees and volunteers. The original language was retained to allow nursing homes to determine what format is most appropriate for their facility, i.e., the first name only, first name and last initial, or first name and last name.

4658.0125 PERSONAL BELONGINGS.

The proposed part 4658.0125 is a revision of the current part 4655.2800. Language was updated to include all personal belongings rather than the previous listing of "wraps, clothing, or other belongings". Also, the term "safe storage" was changed to "storage"; it is necessary to revise this term to reflect that the nursing home must provide a place for storage of employee belongings, but it is not necessary to state in rule that the place be "safe" because these rules are not intended to regulate business practices, nor protect nursing home employees from theft. The language being proposed is reasonable because it continues to require provision for storage of belongings, to keep them separate from resident space.

4658.0130 EMPLOYEES' PERSONNEL RECORDS.

The proposed part 4658.0130 is a revision to the current part 4655.4400. It is necessary to revise this section because of changes in other regulations in the years since these rules were originally promulgated. Several items in the current rule were not included in this proposed part because of changes in other federal and state laws, including the federal Americans With Disabilities Act of 1990 (ADA), [42 U.S.C. §12101 et seq.], which address employees and privacy of personal information. It is reasonable to include a list of items to be included in the personnel records to specify the minimum elements necessary for employee identification for purposes of licensing and surveying for compliance with these rules. These items are necessary in the event the Department needs to contact employees outside of the nursing home, and to verify their qualifications, start and end dates of employment. Nursing homes may certainly choose to gather and include other information in the employee personnel records as is appropriate, but are not required to do so for purposes of compliance with these state licensing rules. Because of 42 U.S.C. §12112 (d)(3)(B), any medical information about an employee is to be considered confidential and as such may not be located in the general personnel record. This provision simply clarifies the nursing home's responsibility to maintain health information separately from other personnel records, although all personnel records are accessible by the Department.

4658.0135 POLICY RECORDS.

The proposed part 4658.0135, subpart 1 is a revision of the current part 4655.4200. The language was revised to require policy records to be available upon request to residents and family members, in addition to nursing home personnel. It is necessary to provide personnel access to policies and procedures to enable them to competently perform their duties and responsibilities. It is also necessary to provide residents and family members with access to those policies and procedures because they are the purchasers of the services being provided by that nursing home, and so have a right to know what is supposed to be provided and how or why. The language being proposed is reasonable because it provides for that access to residents

and family members without causing any undue burden on the nursing home; they are already required to have policies and procedures on file, and merely will need to make those items available upon request to additional persons.

The proposed part 4658.0135, subpart 2 corresponds with the additions to the language in subpart 1 of this part. This new language is necessary to enable the nursing home to provide information to prospective residents, their family and other interested persons on the admission policies of that nursing home. This can be expected to enable consumers to make a better choice of which nursing home to select, based on the resident's needs and the particular characteristics of nursing homes, such as the services provided, facility policies, any specialization of services, population, and so on. It is reasonable to add this language to the state licensing rules to provide for greater consumer information on the nursing home; these policies are already required to be in place so it is simply a matter of making them available to prospective consumers upon their request.

4658.0140 TYPES OF ADMISSIONS.

The proposed part 4658.0140 is a revision of the current part 4655.1500. Subpart 1 was revised by adding the medical director to the persons who cooperate to make admission policies and decisions. It is necessary and reasonable to add that language here because the requirement of a medical director is new to the state licensing rules, and it is appropriate that the medical director be involved in establishing the admission policies of the nursing home. Other parts of the proposed rules address the role and responsibilities of the medical director; this would be a new section in the state licensing rules, based on the federal certification language and current standards of practice developed by medical directors.

It is reasonable and appropriate to have the medical director, along with the director of nursing, cooperate with the administrator to make decisions on admission policies and on the type of residents admitted to the nursing home because the nursing home must be able to meet residents' needs upon admission. If a prospective resident requires a service which the nursing home is not able to provide, it is best to have that information available in policy prior to the prospective admission. Those admission policies must be in compliance with existing federal and state law addressing the rights of individuals, such as the federal Americans With Disabilities Act, the state Human Rights Act (Mn.Stat. Chapter 363), and all other applicable federal and state laws. The admission policies may not unlawfully discriminate on the basis of a person's disability. Nursing homes may choose to specialize in the cares or services they provide. Based on the way the nursing home is staffed, or the layout of the physical plant, or other factors, the nursing home may not be able to meet the needs of all potential residents. Based on those limitations, the nursing home would establish admission policies to clarify the services they are able to provide or the types of residents for whom the nursing home is able to provide necessary and appropriate services.

The proposed subpart 2 is necessary to provide protections to current and prospective residents' health, safety, comfort, treatment, and well-being. The second sentence is new language, added by residents and resident advocates to reasonably provide consumer information on why an admission to the nursing home was denied. Often prospective residents or their families have

no idea why an admission was denied, and it could be that there were no empty beds, the resident requires services which the nursing home is unable to provide, or some other reason for the denial. It is good business sense to provide that information to the prospective resident.

4658.0145 AGREEMENT AS TO RATES AND CHARGES.

The proposed part 4658.0145 is a revision to the current part 4655.1600, and incorporates federal certification language from the section on resident rights. It is necessary and reasonable to require a written agreement between the nursing home and the resident as to the basic rates and services provided by the nursing home in their per diem, or daily rate, and what additional or alternative services may be purchased outside of that basic rate, in order that there be clear understanding on both parts on what can be expected to be provided. The language in subpart 1 is necessary to provide protections to the nursing home and to the resident: there needs to be up-front knowledge of the costs, conditions, and arrangements for the buying and selling of nursing home services. The language is reasonable because it clearly specifies what type of information must be included in the written agreement and what is expected of the billing process.

The proposed subpart 2 is based on federal certification language, and is necessary to ensure that residents are informed when there are changes in the rates charged by the nursing home for the basic services and any additional services which may be purchased from the nursing home. The language is reasonable because it matches that federal language which all certified facilities must comply with, and is a good business practice.

4658.0150 INSPECTION BY DEPARTMENT.

The proposed part 4658.0150 contains the language in the current part 4655.2300, updated to replace "shall" with "must", and removing the term "patient".

4658.0155 REPORTS TO THE DEPARTMENT.

The proposed part 4658.0155 contains language from the current part 4655.3800, with the term "shall" replaced by the term "must". The third sentence of the current rule is not included here because it is not necessary to include specifications of business practices in the licensing rules.

4658.0190 PENALTIES FOR ADMINISTRATION AND OPERATIONS.

See the discussion regarding the establishment of penalty assessment levels under part 4658.0045 above.

Penalty assessments for current rule language which has been renumbered or only editorially revised have not been changed. This includes the proposed parts 4658.0050, 4658.0055, 4658.0060, 4658.0065, 4658.0075, 4658.0085, 4658.0090, 4658.0095, 4658.0100, 4658.0110, 4658.0115, 4658.0120, 4658.0125, 4658.0130, 4658.0135, subpart 1, 4658.0140, 4658.0145, subpart 1, 4658.0150, and 4658.0155.

The proposed penalty assessment for noncompliance with a correction order for part 4658.0070

is $100. This fine is consistent with fines for related topics within this rule. The functions of the proposed quality assessment and assurance committee (based on federal regulations) are closely related to the functions of the current patient care policy committee, and most likely the same nursing home staff serve on the two committees. In fact, many nursing homes operate one committee that serves to comply with both the federal and the state regulations. While noncompliance with this provision need not necessarily create a substantial risk of harm, the failure to comply has the potential for jeopardizing the health, safety, treatment, comfort, or well-being of residents. It is appropriate that the penalty assessment for this proposed part be consistent with penalty assessments for other rule parts that address issues related to the administration and management of the nursing home.

The proposed penalty assessment for noncompliance with a correction order for part 4658.0080 is $100. Again, this proposed rule part is related to the administration and management of the nursing home. Noncompliance with this proposed provision, that of notifying the applicable professional board whenever a licensed provider is providing what amounts to substandard or potentially neglectful care, has the potential for jeopardizing the health, safety, treatment, comfort, or well-being of residents. It is appropriate that the penalty assessment for this proposed part be consistent with penalty assessments for other rule parts that address issues related to the administration and management of the nursing home.

The proposed penalty assessment for noncompliance with a correction order for part 4658.0105 is $300. The $300 penalty assessment has been assigned to those rules which are necessary to assure that the service is properly provided, e.g. staffing, general orientation and inservice requirements, development of policies and procedures governing the provision of care, availability of equipment and supplies, etc. Noncompliance with these rules would affect the quality of care that is provided to the residents. This rule, addressing the competency of direct care staff, is directly related to the actual provision of services and compliance with the rule is necessary to assure that the actual provision of services by direct care staff is done in a safe and effective manner. Noncompliance with this rule would result in the inability to adequately meet the needs of the residents and the Department believes that the $300 fine is appropriate.

The proposed penalty assessment for noncompliance with a correction order for part 4658.0135, subpart 2 is $50. Noncompliance with a correction order would not directly jeopardize the health, safety, treatment, comfort, or well-being of a residents. While this rule is a required minimum standard necessary to promote the proper operation of the nursing home, the potential for harm presented to residents as a result of noncompliance is not direct. The Department believes that the establishment of the $50 level as the minimum fine is appropriate. This minimum fine level conforms with the legislative standard that the schedule of fines take into consideration the potential for harm to residents and, at the same time, establishes a sufficient sanction for a nursing home's failure to comply with a correction order.

The proposed penalty assessment for noncompliance with a correction order for part 4658.0145, subpart 2 is $100. This fine level is assigned to those rules which relate, in a general nature, to the administration and management of the nursing home. While noncompliance with this rule part need not necessarily create a substantial risk of harm, the failure to comply has the potential for jeopardizing the health, safety, treatment, comfort, or well-being of residents. For example,

the failure to inform residents of an increase in the charge for a service not included in the per diem rate can result in the resident not having sufficient funds for that service when the resident requests it. This informing persons of the charges for services offered is a normal part of operations for a service business, and is a reasonable consumer expectation for nursing home services.

The penalty assessments for these rule parts are consistent with penalties for related topics found in other rule parts. They are reasonable because they take into consideration the potential for harm to residents while at the same time establishing sufficient sanctions to ensure compliance with applicable statutes and this rule chapter.

RESTRAINTS

PART 4658.0300 USE OF RESTRAINTS.

The proposed part 4658.0300 is a revision of the language currently found in part 4655.6600. It has been amended to match more closely with current federal regulatory language, and has been expanded to include necessary clarification of terms and situations. It is necessary to revise this part to more clearly address the use of restraints in nursing homes - when they may be permitted, what are considered restraints, and what actions the nursing home must take when restraints are being used. Restraint use is an issue which elicits many comments and opinions, and so it is reasonable to clarify the requirements relating to the use of restraints to provide clear and appropriate information to consumers, providers, and regulators. There are federal laws and regulations addressing the use of restraints in nursing homes. However, the members of the public workgroup which reviewed these regulations and the members of the Steering Committee deemed it appropriate to also include these regulations in state rule in order to protect the health and safety of residents. Across the country nursing home staff have sought ways to reduce the inappropriate use of restraints. "In recent years, long-term care providers, residents and families have seen significant changes in the approach to using restraints. Extensive medical and nursing research has cast doubts on the customary use of restraining devices and antipsychotic medications when used as chemical restraints. Increasing attention to promoting the dignity and independence of the frail elderly has encouraged physicians and facility staff to consider their policies on restraint use."[1]

There have been many articles and documents written in the last several years regarding the use of restraints and the need for a reduction in the use of restraints. There are several risks associated with the use of restraints. These include: serious injuries, including accidental hanging; psychological damage; loss of freedom, control, independence, loss of self-esteem, depression, hopelessness, helplessness; loss of mobility, leading to contractures, muscle loss and

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[1] "Clinical Practice Guidelines for the Use of Restraints," American Health Care Association, January 1992.

weakness; pressure sores, skin breakdown; incontinence, inability to toiled as needed; chronic constipation; increased agitation; increased dependency; and increased confusion.[2] Many professionals and organizations have decried the use of restraints. "Both mobility and personal autonomy are threatened by the use of involuntary restraints. No controlled trial has yet demonstrated the ability of restraints to prevent injury, but a large body of literature attests to their adverse effects, including strangulation, increased agitation, and the many complications of immobilization."[3]

In the article, "Alternatives to Physical and Pharmacologic Restraints in Long-Term Care, the authors write,

> "Recently, a mounting wave of public criticism has been directed at the use of restraints. Studies have shown that physical restraints to not reduce injuries and that both physical and pharmacologic restraints are associated with a variety of adverse effects, including excess physical disability, more frequent falls and problems related to immobility, such as diminished muscle mass, the development of decubitus ulcers, constipation and thrombophlebitis.
>
> Both types of restraint measures can cause or aggravate behavioral symptoms, such as worsened confusion and agitation among physically restrained residents, and extrapyramidical reactions and tardive dyskinesias among residents receiving psychotropic medications. In addition, physical restraints have been implicated as risk factors for nosocomial infection, death, and injury due to improper use of restraints, while psychotropic medications frequently contribute to adverse drug reactions. Finally, because restraints infringe on the residents' personal liberty and are often administered against the residents' wishes - at times over overt and continued objections - the choice to use such measures must be made cautiously."[4]

Current federal law addressing the resident right of freedom from restraints took effect on October 1, 1990. Some of the language used in this proposed rule comes directly from that federal law, or from the federal requirements for participation to enact that law. On March 5, 1992, the federal Health Care Financing Administration published proposed rule provisions which include the use of physical and chemical restraints in nursing homes. These proposed rule revisions have not yet been finalized nor promulgated as final rule. They continue to undergo review by the federal Health Care Financing Administration. The proposed state revisions are less extensive than those proposed federal revisions, and do not conflict with them. When those proposed federal revisions are finalized, the Department will review them along with our state

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[2] "The Use of Restraints in Nursing Homes - A Guide for Residents and Families", from the Colorado Ombudsman Program.

[3] J. Francis, "Using Restraints in the Elderly Because of Fear of Litigation," New England Journal of Medicine, 320, no. 13 (1989): 870)

[4] Sloane, P., Papougenis, D., Blakeslee, J., "Alternatives to Physical and Pharmacologic Restraints in Long-Term Care," American Family Physician, vol. 45, no. 2, February 1992: 763.

rules for any necessary rule revisions which may occur then.

Subpart 1: The language in the proposed part 4658.0300, subpart 1 provides definitions of the terms used in subsequent subparts. It is necessary and reasonable to define the terms used in the rule so that consumers, providers, and regulators have a common, specific definition to follow when interpreting the rule. The public workgroup reviewing this section of the rules told the Department that it was important to base the state rule here on the federal regulation, and to add definitions of the terms used so the rule would be easier to understand and to implement. Generally, the language used in these definitions is derived from existing federal regulations and the interpretive guidelines for those regulations.[5]

Subpart 2: The proposed 4658.0300, subpart 2, provides the fundamental basis for this rule part. It is necessary to state in the rule the resident right to be free from misused and overused restraints, whether physical or chemical restraints, and free from corporal punishment and involuntary seclusion. It is reasonable to require that physical or chemical restraints must not be used for discipline nor convenience (misuse), nor if they are not required to treat the resident's symptoms (which could be misuse or overuse). Corporal punishment and involuntary seclusion are not allowed because they also infringe on residents' rights. This statement is the standard of practice for appropriate use of restraints in nursing homes at this time. The language comes from the federal law and regulations, so 99% of the licensed nursing homes in Minnesota are already required to comply with this language.

Subpart 3: The proposed revisions expand on the existing state rule language currently found in the current part 4655.6600. The revisions to this subpart are necessary to enhance and clarify resident rights when restraints are used, and to specify provider responsibilities for the safe and appropriate use of restraints. The language being proposed is reasonable because it adds a requirement for the notification of the resident's legal representative or interested family member when a resident requires temporary, emergency measures to protect him or herself and other persons in the nursing home. These revisions serve to protect the resident. The current language was also revised by adding a requirement that physician orders must specify the duration and circumstances when restraints may be used. This proposed revision is necessary to ensure that restraints are used appropriately and not for discipline, staff convenience, or in the absence of medical symptoms necessitating them.

Subpart 4: This proposed subpart clearly states the minimum requirements to the nursing home for the use of restraints on any resident. It is necessary to state these requirements in rule in order to have a clear set of standards by which restraint use may be conducted and evaluated, in order to protect the health, safety, comfort, treatment, and well-being of the residents. "Protective restraints provide benefits to many patients when used for indicated circumstances, such as precluding patients with temporary or medical-related cognitive deficits from impairing the resolution of their physical problems by involuntarily discontinuing life-support or other needed medical interventions, temporarily reducing the mobility of agitated patients who may

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[5] See Appendix P, "Guidance to Surveyors - Long Term Care Facilities," State Operations Manual, U.S. Health Care Financing Administration, April 1992.

otherwise hurt themselves, or helping patients feel safer in a bed or wheelchair."[6] The language being proposed is reasonable because it provides clear standards which provide protections for the resident, while it also coordinates with existing federal regulatory language dealing with restraint use. Proposed language ensures that the nursing home follows a systematic approach before and during the use of restraints to assure resident safety.

The statement on not requiring residents to be awakened is new language (not currently in state nor federal regulatory language). It is necessary and reasonable to add this statement about awakening residents because information provided to the Department suggests that residents have been awakened by nursing home staff lowering and raising bed rails in the middle of the night. This practice is allegedly being done to comply with a proposed federal regulation which would require a release from the restraints every two hours. The Department agrees that releasing restraints is important, but raising and lowering bedrails may not always be necessary during sleeping hours, and can be detrimental to the well-being of the residents, especially if the ritual of raising and lowering the bed rails would wake the resident. Because bed rails are often used as the least restrictive means of restraint, especially during night time hours, and because other types of restraints may be used on sleeping residents, it is necessary for the rules to clearly state that these proposed rules do not require the wakening of residents.

4658.0310 PENALTIES FOR USE OF RESTRAINTS.

4658.0300, subpart 2: The penalty assessments for noncompliance with correction orders addressing part 4658.0300, subpart 2 have been set at $500. This subpart states that residents must be free from any physical or chemical restraints imposed for purposes of discipline, and not required to treat the resident's medical symptoms, and free from corporal punishment and involuntary seclusion. The $500 fine amount is reasonable because noncompliance with this rule part would present an imminent risk of harm to the comfort and well-being of residents. Continued noncompliance with these rules would create a substantial probability that a resident would be subjected to serious physical, mental, or psychosocial harm. The maximum fine is appropriate and necessary to fully protect nursing home residents.

Subpart 3: The penalty assessments for noncompliance with correction orders addressing part 4658.0300, subpart 3, items A and B, have been set at $500. These portions of the rule address situations where temporary, emergency measures must be taken to protect the resident or others. The $500 fine amount is reasonable because noncompliance with this rule part would present an imminent risk of harm to the comfort and well-being of residents. Continued noncompliance with these rules would create a substantial probability that a resident would be subjected to serious physical, mental, or psychosocial harm. The maximum fine is appropriate and necessary to fully protect nursing home residents.

The penalty assessments for noncompliance with correction orders addressing part 4658.0300, subpart 3, item C, have been set at $50. This item is the requirement for notification of the resident's legal representative or interested family member when temporary, emergency

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[6] Proposed FDA Regulations on Restraints, Federal Register, Vol. 57, No. 119, Friday, June 19, 1992:27398.

measures are taken. The $50 fine is reasonable because noncompli... ...art would not directly jeopardize the health, safety, treatment, comfo... ... resident. While these rules are required minimum standards necessary to pro... ... operation of the nursing home, the potential for harm presented to resid... ...ompliance is not direct. This minimum fine level conforms with the legislativ... ...e schedule of fines take into consideration the potential for harm to resid... ...me time, establishes a sufficient sanction for a nursing home's failure to compl... ...ion order.

Subpart 4: The penalty assessments for noncompliance with correct... ...ssing part 4658.0300, subpart 4, item A, have been set at $250. The $250 pena... ...s assigned to those rules and statutes that are related to the protection of the in... ...residents. This rule item requires the nursing home to obtain an informed ... ...placing an individual in a restraint. This provision is designed to assure tha... ...rights of residents are promoted and protected in the nursing home. A violati... ...sion could jeopardize the well-being of residents and could also jeopardize the re... The rules are necessary to assure that the residents' rights to privacy and ... ...quate and considerate care are fully protected. The $250 fine is appropriate to a... important interests are fully protected within the nursing home.

The penalty assessment for noncompliance with correction orders a... ...658.0300, subpart 4, item B, has been set at $300. This item requires a writte... ...e attending physician for any restraint applied to a nursing home resident. Th... ...ssment has been assigned to those rules that are necessary to assure that the ser... ...provided. Noncompliance with these rules would affect the quality of care that is... ...residents. These rules are directly related to the actual provision of the servic... ...with these rules is necessary to assure that the actual provision of the servi... ...d effective manner. Noncompliance with this proposed rule regarding physician ... ...ints would result in the inability to adequately meet the needs of the residents an... ...nt believes that the $300 fine is appropriate.

The penalty assessments for noncompliance with correction orders a... ...4658.0300, subpart 4, items C, D, E, and F have been set at $500. These items r... ...the nursing home is required to make when a restraint has been applied to a reside... ...um penalty assessment of $500 is assigned to those rules and statutes for wh... ...nce with a correction order would present an imminent risk of harm to the h... ...t, comfort, safety, or well-being of nursing home residents. Continued nonc... ...these rules would create a substantial probability that a resident would be sub... ...s physical, mental, or psychosocial harm. A violation of the provisions listed i... ...gh F of the proposed 4658.0300, subpart 4, justifies the maximum fine due t... ...l for harm presented to the resident by noncompliance with these provisions ... ...um fine is appropriate and necessary to fully protect nursing home residents pl... ...ts.

The penalty assessments for noncompliance with correction orders ... ...4658.0300, subpart 4, item G, has been set at $300. This item requires a re... ...of restraint usage and checks on the resident. The $300 penalty assessment has b... ...those rules that are necessary to assure that the service is properly provided. ... ...e with these

rules would affect the quality of care that is provided to the residents. This rule item is directly related to the actual provision of the service (checking the resident during times when restraints are applied), and compliance with these rules is necessary to assure that the actual provision of the service is done in a safe and effective manner. Noncompliance with these rules would result in the inability to adequately meet the needs of the residents and the Department believes that the $300 fine is appropriate.

COMPREHENSIVE RESIDENT ASSESSMENT AND PLAN OF CARE

PART 4658.0400 COMPREHENSIVE RESIDENT ASSESSMENT.

This part is being proposed to be included in the state licensing rules for nursing homes to delineate the expectations for a comprehensive assessment of each resident's needs. This comprehensive assessment is to be the basis for the development of the resident's plan of care, and for the cares the resident receives in the nursing home. Because this would be a new area in the nursing home licensing rules, the language being proposed is fairly descriptive of what must be included in the comprehensive assessment.

It is necessary to include a section in the licensing rules on the comprehensive resident assessment to incorporate the concept of a continuum of assessment, development of a plan of care to address the resident's needs, the provision of those cares, and a periodic review of the resident's condition and need for reassessment.

Subpart 1: A comprehensive assessment of each resident's needs is essential to the provision of appropriate services by the nursing home. It is necessary to add the proposed language to state licensing rules for nursing homes to ensure that these assessments are conducted at critical points of the resident's stay so that the nursing home is aware of the needs of each resident, and takes into account the changing status of that resident's condition. Conducting assessments is considered good practice in all the disciplines providing services in the nursing home. A requirement for an assessment is included in the federal Requirements for Participation for the Medicare and Medicaid programs. The language being proposed matches that federal regulatory language. It is necessary and reasonable to state in rule the purpose of conducting the comprehensive resident assessment, namely to develop, review, and revise the comprehensive plan of care. By stating the intended use of the assessment, we hope to underscore the intended link between conducting assessments, developing a plan of care, implementing the plan of care, doing quarterly reviews of the residents, and reassessing the resident to assure the continued accuracy of the assessment and the plan of care. This process leads to a continuum of care designed and provided to meet the changing needs of the individual resident.

Subpart 2: It is necessary to list in rule the minimum components of the comprehensive resident assessment to ensure that nursing homes are aware of the major conditions affecting

each resident, or their status in the various listed areas. By ascertaining the status of the resident, his or her needs for services can be determined. From this information, the nursing home can plan for ways to provide the necessary services. The results of this comprehensive resident assessment are used to develop, review, and revise the comprehensive plan of care for each resident. The language being proposed is reasonable because it lists the basic areas of the resident's status to be considered when planning cares, without being specific as to how those items are assessed nor how extensive the assessment must be. Current federal regulatory language also requires a comprehensive assessment, and requires states to designate a form containing the minimum data elements of the assessment; that form must be used by all certified nursing facilities when they conduct those assessments. This proposed state language does not require the use of any specific form nor format, however, the form used for the federal comprehensive assessment does contain all the listed elements and would fulfill this requirement.

Subpart 3: It is necessary to state in rule the required frequency of the comprehensive resident assessments to capture the relevant information with which the comprehensive plan of care is developed and maintained. The proposed language is reasonable because it requires assessments within 14 days of admission, so the plan of care can be initially developed; after a significant change in the resident's condition, so the care plan can be revised to address the change in condition; and at least once every 12 months, to assure that the care plan does address the resident's current condition. Without the initial assessment, care plans would likely be incomplete and so could be detrimental to the well-being of the resident. When a resident's condition changes, whether an improvement or a decline, the comprehensive assessment needs to be redone to account for that change, so the nursing home can adjust the plan of care and the services being provided for that resident in order to best meet the resident's needs. And, a comprehensive assessment must be conducted no less often than once every 12 months to ensure that it continues to reflect the resident's current condition so that the resident will receive the necessary cares. The language being proposed matches the federal certification language.

Subpart 4: It is necessary to state in rule that residents must be examined by the nursing home at least once every 3 months so the resident's condition is being monitored and assessments can be redone in a timely manner if necessary. The language being proposed is reasonable because it fits into the assessment / care planning / implementation process which nurses traditionally follow, and because it matches federal certification language which 99% of the nursing homes in Minnesota already comply with.

PART 4658.0405 COMPREHENSIVE PLAN OF CARE. ..

This part is proposed to be included in the state licensing rules for nursing homes to delineate the expectations for a comprehensive plan of care. This comprehensive plan of care is to be the basis for the design and provision of the cares the resident needs and receives in the nursing home. The language being proposed is fairly descriptive of what must be included in the comprehensive plan of care because this is a new focus for the state licensing rules, i.e., developing a plan of care to address all the resident's needs, not only the nursing needs. There has been a state rule on the nursing care plan; that would be incorporated into the comprehensive plan of care, along with plans for other services.

It is necessary to include a section in the licensing rules on the comprehensive plan of care to incorporate into rule the concept of a continuum of comprehensive resident assessment, development of a plan of care to address the resident's needs, the provision of those cares, periodic review of the resident's condition, and reassessment. This continuum is a part of appropriate nursing practice, and ensures that the nursing home is aware of and is addressing the needs of the residents.

Subpart 1: It is necessary to state in rule the requirement that a comprehensive plan of care be developed for each resident to ensure that the cares provided are appropriate for and meet the needs of that resident. The language being proposed is reasonable because it reflects common practices of planning for cares to be provided, while allowing flexibility to the nursing home to develop that care plan. The fundamental items to be included in the care plan are listed in the subpart. The timeframe for development of the comprehensive plan of care for each resident matches the timeframe allowed in current federal certification requirements. These can be the same comprehensive plan of care for those nursing homes which are both licensed and certified. In other words, this plan of care would meet both the federal and the state regulations.

Subpart 2: It is necessary to include a subpart in state licensing rules about the use of the plan of care in order to assure that consumers, providers, and regulators are informed of the purpose of and the expectations for the use of the plan of care. The plan of care is needed to guide the course of treatment for each resident. The current rules require the development and use of a plan of care, so this is not a new requirement for nursing homes. The language being proposed is reasonable because it states the requirements in an easier-to-understand manner than the current language.

The timeframes provided for review and updating the comprehensive plan of care are necessary to provide benchmarks of the resident's needs. Those timeframes are reasonable because they correspond with other state and federal regulations which require a review of the resident at least every 90 days (or quarterly, as some regulations state), and when there is a significant change in the resident's condition. These timeframes are reasonable to provide protection for the resident and an assurance that their current condition is being addressed, whether it has improved, declined, or stayed the same.

4658.0420 PENALTIES FOR COMPREHENSIVE ASSESSMENT AND PLAN OF CARE.
See the discussion in part 4658.0045, above.

The fines for noncompliance with correction orders for parts 4658.0400 and 4658.0405 have been established in accordance with the 8 tier level of fines developed to correlate with the impact of noncompliance on the resident. The penalty assessments are set at $300 for both parts. This level of fine is assigned to those rules which are necessary to ensure that services are properly provided by the nursing home. The comprehensive assessment and plan of care are the basis for the services to be provided by the nursing home. These rules are directly related to the actual provision of those services and compliance with these rules is necessary to assure that the actual provision of the services is done in a safe and effective manner. Noncompliance with these rules would result in the inability to adequately meet the needs of the residents and the Department believes that the $300 fine is appropriate.

CLINICAL RECORDS

The proposed parts 4658.0430 through 4658.0490 are revisions to the current parts 4655.3200 through 4655.3900, as well as other parts of Chapter 4655 which address clinical records. It is necessary to revise these parts in order to incorporate current practices and standards of practice. It is reasonable to revise these rule parts to cluster the rules addressing clinical records and health information management.

PART 4658.0430 HEALTH INFORMATION MANAGEMENT SERVICE.

Subpart 1: It is necessary to include a rule part requiring a health information management service to assure that the nursing home will properly maintain information on each resident necessary to provide services to each resident. The language includes references to accepted professional standards and practices and to the other federal and state regulations which impact on health information. It is reasonable to require that health information be maintained for residents to facilitate the transfer of information to appropriate nursing home staff, other health professionals providing services to the resident, provide for continuity of care, to enable the evaluation of appropriateness and effectiveness of resident cares and services, to facilitate billing, and provide documentation for survey and compliance purposes. The language being proposed is also reasonable because it states a general requirement which nursing homes have been required to comply with under existing state and federal regulations. There should be no impact on nursing homes with the proposed revisions because the intent of the regulation has not been changed. In 1991, the American Medical Record Association voted to change its name to the American Health Information Management Association. The reason that organization changed its name was, "to reflect the profession's recognition of the fundamental evolution in its role as the focal point of responsibility for the most vital documentation in the healthcare system - the patient's medical information."[7]

Subpart 2: Part of an effective health information management service is a method of quality assurance for the service. It is necessary to state in rule this mechanism for auditing the quality of the service to provide protection for resident data and ultimately to help ensure that the resident's needs are known and are being addressed. The proposed language is reasonable because it allows the nursing home to determine what kind and how extensive a mechanism to develop and utilize to audit the quality of the service. Because so much of the care the resident receives is dependent upon accurate information in the clinical record, it is appropriate that the rule include a statement addressing the need for auditing the quality of that information.

Subpart 3: It is necessary to require that there be a person designated as responsible for health information management in order to assure that the service is provided and managed appropriately. Because the health information management needs of the nursing homes in Minnesota vary greatly, the Department is not specifying any particular professional or educational background for the person responsible for health information management. Rather, the nursing home must determine what are the qualifications necessary for the person in charge

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[7] Journal of American Health Information Management Association (AHIMA), Vol.62, No.11, November 1991: p.25.

of their clinical records, or, health information, and then must have a suitably qualified person in that position. It is reasonable to require that there be a person designated as responsible for this service because it is an important part of the package of services provided by the nursing home, and because health information management covers such a wide scope of issues. There are federal and state laws dealing with confidentiality of health care data, as well as professional standards of practice advocated by a variety of groups of professional records management persons. These laws must be followed, and the standards could be very helpful in the proper provision of a health information management service.

PART 4658.0435 CONFIDENTIALITY OF CLINICAL RECORDS / INFORMATION.

Subpart 1: The proposed language is patterned after current language in 4655.3500, subpart 3. It is necessary and reasonable to include in these rules a requirement that clinical records be kept confidential because confidentiality is a requirement of other various state and federal statutes which are stated in the rule. By citing these statutes in the rule we are intending to ensure that nursing homes are able to locate and be aware of those applicable regulations to ensure that resident records are maintained and utilized in a confidential manner. We are including the cites in the rule to provide clarification to nursing homes on which specific state statutes apply to confidentiality as a resident right. For example, Minnesota Statutes, §144.651, subdivision 16, protects the confidentiality of personal and medical records maintained by health care facilities. Minnesota Statutes, §144.335, protects the residents' right to access health information and controls the release and transfer of that information.

Subpart 2: There are nursing homes which make use of facsimile machines to transmit and receive health care data. Since electronic transmission of health care data is a new occurrence since the original nursing home licensing rules were written, it is necessary to include a part in these proposed rules for those nursing homes which choose to transmit or receive health care data by facsimile machine. This proposed language is reasonable because it addresses the need for policies and procedures dealing with the use of the facsimile machine to ensure the confidentiality of that resident information. It is reasonable to require nursing homes to develop and comply with policies and procedures because they are required to maintain confidentiality of that information under other applicable state laws. Nursing homes need to be aware of confidentiality issues which arise with the use of facsimile machines, such as locating the machine in a secure, private area, verifying the telephone number being used to transmit data to, and resident authorization for release of information. The nursing home policies and procedures can reasonably be expected to address issues such as these.

PART 4658.0440 ABBREVIATIONS.

It is necessary to require that nursing homes have an explanation key for abbreviations or symbols used in documentation and the collection of data and information to assure the accuracy and consistency of that data and information. There are a number of terms which can be abbreviated as the same initials or symbol which have widely different meanings to different professionals or different persons within a profession. It is reasonable to require an explanation key so that all staff documenting information into the resident record or collecting other data and information are using the same initials or symbols for terms so that all staff, or other authorized persons reviewing the information, will have a consistent explanation for the information.

PART 4658.0445 CLINICAL RECORD.

Subpart 1: It is necessary and reasonable to require that a clinical record be initiated for each resident on admission to assure that the record exists right away and includes information vital to provide appropriate services to that resident. The proposed language is based on portions of the current chapter 4655. The language proposed here is reasonable because it incorporates documentation required by other parts of the rules into the central unit record system. In other words, it describes where and what information must be included in an individualized clinical record for each resident, as part of a central record system for maintaining information on all residents. The data required are not new; these elements have all been required and it is reasonable to expect that all these elements have been contained within the existing clinical record maintained on each resident.

Subpart 2: It is necessary to establish standards for the entry and authentication of data into the clinical record to assure that the data is accurate and entered in a timely manner, to protect the resident from any outcomes of incomplete records. These outcomes may include over- or under-medication, missed treatments, failure to recognize changes in condition, or many other possible problems. The language being proposed is reasonable because it follows standards of practice established by clinical records professionals while allowing more leeway for the form of entries. The current rule (MN Rules 4655.3200 Subpart 2) states, "All entries shall be made with a pen..." The proposed language will allow for technological advances in record-keeping such as computerized clinical record systems, while still allowing the traditional handwritten charting methods. Nursing homes will still be required to have methods for verification of the person making the entry, and safeguards for unauthorized use, regardless of the method of entry used.

One other change to the rules would be the allowing of nursing assistants to document in the nursing notes, if the nursing home has developed a policy allowing that practice. In the course of gathering public suggestions regarding the revision of these rules, the Department heard many times that the nursing assistants are the providers of the majority of cares to most nursing home residents. As such, in some cases the nursing assistant is the most appropriate person to be chronicling the resident's condition, treatments, and so on. The proposed language is reasonable because it would allow the nursing home to determine if it would want to allow documentation in the nursing notes by nursing assistants, and if so, the nursing home must develop a policy allowing and addressing that practice.

Subpart 3: It is necessary to include in this proposed rule a subpart requiring accurate documentation of diagnoses and procedures to assure the health, safety, comfort, and well-being of the residents. There is no requirement in this section of the proposed rules addressing the educational nor experiential background of anyone on the clinical records staff. Therefore it is necessary to, at a minimum, require that this technical information entered into the record is reliable, again to protect the resident. The proposed language is reasonable because it is a part of normal operations of a clinical records service and is an accepted professional practice.

Subpart 4: It is necessary to include a part in these proposed rules on the minimum information collected and maintained upon admission for each resident in order to specify the essential

compliance purposes. This minimizes confusion and inaccuracies in the administration of medications and treatments and any relevant observations by allowing nursing home staff and other care providers to quickly refresh their memories with respect to the care and services ordered for and received by the resident. Generally, the items included in this proposed part are in the current rule, although they may have been located in separate parts of that rule. The revisions attempt to pull together the various items to be included in the clinical record from the various disciplines responsible for providing care, treatment, and services to the resident.

4658.0455 TELEPHONE AND ELECTRONIC ORDERS.

It is necessary and reasonable to include specific rules on orders being received by the nursing home by telephone, facsimile machine, or other electronic means in order to protect the confidentiality of the resident information and to assure the accuracy of that information.

Item A is necessary to convey the fact that orders received by telephone or other electronic means do fall under pre-existing statutes addressing the confidentiality of health care information. As such, if the nursing home decides to accept orders by telephone, facsimile machine, or other electronic means, they must have methods or procedures to maintain the confidentiality of that information. The language proposed is reasonable because it informs the public of the location of those applicable statutes.

Item B is necessary to assure that the nursing home appropriately places orders received by telephone or other electronic means into the resident's clinical record ("immediately" and "by the person authorized by the home"). Also, those orders must be countersigned by the ordering physician, dentist, or other health practitioner licensed to prescribe, at the time of the next visit by that person, which is necessary and reasonable to verify the accuracy and authenticity of those orders. Based on numerous discussions on this topic, the proposed rules no longer include the requirement for countersigning within seven days. Physicians, dentists, nurse practitioners, nursing staff, residents, and consumer advocates all tended to agree that the current requirement has become merely a paper compliance issue, where there are lots of resources going into getting those orders back to the ordering health practitioner (most frequently, the physician) as quickly as possible, and the health practitioners are countersigning the orders often without reviewing them. Rather than continue to require the countersigning within seven days, the proposed rules require countersigning at the time of the next visit. Providers stated that if there is an error in the order as it is recorded or placed in the resident's record, the nursing staff should be able to spot the error and contact the ordering health practitioner immediately for a correction.

Item C, requiring any orders sent by facsimile machine, or faxed, to the nursing home to have been signed by the ordering health practitioner licensed to prescribe, is necessary to provide guidance to nursing homes on the appropriate authorization of those orders. It is necessary to require the signature of the health practitioner licensed to prescribe on the original paper (at the site of the originating facsimile machine) so that the fax copy received by the nursing home shows that the physician, dentist, or other health practitioner actually did order something for the resident. The language being proposed is reasonable because it sets easily implementable standards for the receipt of faxed orders in the nursing home. These faxed orders would not need to be countersigned because they would already have the authorizing signature on them.

elements of the clinical record necessary to identify the resident and to have background information available to nursing home staff. The proposed language is based on the current part 4655.3500, subpart 1, and is updated to reflect current standards of practice. It is reasonable to require this information to be collected upon admission to provide protection and assurance to the resident that he or she is known to the nursing home and the nursing home has information on persons to contact for various reasons or situations, any advance directives the resident has specified, and some basic information about the resident. It is reasonable to require these minimum data elements to be included in the clinical record in order to have them located together in a central, readily accessible location so that staff would not have to go searching for this information, but rather would be able to pinpoint it fairly easily. The data elements included are not new items; nursing homes traditionally have maintained this information under existing state and federal regulations and facility policies.

In addition, we are proposing to add to the rule language a reference in the clinical records section to other rule sections which address information to be stored or maintained in the resident's clinical record. The specific locations of those other rule sections, located within the rule parts for various services, are cited in this proposed rule.

4658.0450 CLINICAL RECORD CONTENTS.

It is necessary to state in rule the contents of the clinical record so that nursing homes are aware of documentation requirements for information, observation, and treatment necessary to assure the appropriate services are provided to residents.

> "The nursing process is a deliberate, problem-solving approach to meet the health care and nursing needs of patients. It involves assessment (data collection), nursing diagnosis, planning, implementation, and evaluation, with subsequent modifications used as feedback mechanisms that promote the resolution of the nursing diagnoses. The process as a whole is cyclic, the steps being interrelated, interdependent, and recurrent...Data collection is the first step in the process of defining problems. A thorough and accurate assessment of a patient's problems or condition depends on the completeness and accuracy of the data collected."[8]

The data elements listed in the proposed rule language are those which provide the basic information on what is significant to the resident's condition, treatment provided, and results obtained. Based on information provided by health information management professionals, the data elements listed are contained in the standards of practice for documentation in the clinical record in nursing homes.

The clinical record is considered a legal document. As discussed above, it is reasonable to require that health information be maintained for residents to facilitate the transfer of information to appropriate nursing home staff, other health professionals providing services to the resident, provide for continuity of care, to enable the evaluation of appropriateness and effectiveness of resident cares and services, to facilitate billing, and provide documentation for survey and

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[8] Suddarth, D.S., The Lippincott Manual of Nursing Practice, J.B. Lippincott Company, 5th Edition, 1991.

4658.0470 RETENTION, STORAGE, AND RETRIEVAL.

Subpart 1: There is no change from current rule language found at Part 4655.3600.

Subpart 2: It is necessary to require space to be provided for safe and confidential storage of resident records to protect the integrity and privacy of those records. This is a basic right of residents - the privacy, or confidentiality, of their health information, which has been discussed previously. It is reasonable to require the records to be maintained in a safe manner so that they are available for future use. This means that consideration can be expected to be given to the location of those stored records, whether the storage location is onsite or offsite. The proposed language would allow for the offsite storage of records of discharged residents, if that location provides for safe and confidential storage of those records. It is necessary and reasonable to specify that records of current residents be stored onsite to allow the ready accessibility of those records to the nursing home staff providing cares to those residents, to assure appropriate services are delivered.

Subpart 3: It is necessary to include a rule requiring policies and procedures on the retrieval of clinical records stored offsite to assure those records are retrievable in a reasonable amount of time, whether for facility staff, residents, or ombudsmen, or for surveyors who need to review the facility's compliance with regulations. There have been situations in the last few years where records have been stored offsite and they were not readily accessible to persons wanting them, so it was recommended that the rules be revised to specifically address the retrieval of records. It is also necessary to require policies to address the location and retention of records if a nursing home discontinues operation. Again, this is in response to situations which occurred in Minnesota in recent years, where residents were transferred to other care facilities without adequate information to provide appropriate and necessary services, and it was not possible to provide continuity of care for those residents. This resulted in some negative outcomes for those residents. The language being proposed is reasonable because it requires policies and procedures for offsite storage which the nursing home can reasonably be expected to address just as a part of good business operations as well as part of compliance with statutes on maintaining confidentiality of clinical records.

4658.0475 COMPUTERIZATION.

The current state rules do not allow for a totally "paperless" health information management system (clinical records). These proposed revisions would allow for a paperless system, as long as the items listed in the rule are addressed by the nursing home. With the advances in technology and the federal requirements regarding the resident assessment instrument (RAI) containing the minimum data set (MDS), a number of nursing homes have begun using a computerized clinical record system. Since this is a new section in the state licensing rules, it is necessary to include specific requirements so that if and when a "paperless" health information management system is established it will include these essential elements. These items are essential to assure accuracy, integrity, and confidentiality of the records. The proposed language is reasonable because it incorporates existing health information management principles into a computerized records system. The language being proposed is based on standards developed by health information services professionals.

An order received by the nursing home in this manner is less likely to be inaccurate than a telephone order because the health practitioner would reasonably be expected to have read it at the time of signature, thus verifying the information prior to its transmission.

4658.0460 MASTER RESIDENT RECORD.

It is necessary to require the nursing home to maintain a permanent master resident record in order that a chronicle is kept of all persons who have been a resident in that nursing home. This is necessary for long-term tracking of persons and to calculate the number of admissions, discharges, deaths, and total resident days in that nursing home. Those statistics are required for state and federal regulatory and payment purposes. The language is reasonable because it is something the nursing home can easily do with existing staff, and in fact has been required to do under current rule. The current language found at Part 4655.3700 states, "A register shall be kept in a separate bound book...." The revision of the proposed language to "A permanent record must be kept..." will permit nursing homes to continue to keep this information in a permanent bound book, or to use a computer file to maintain this information (which allows for faster and easier calculation of statistics and sorting and formatting of the data), or to have some other system which allows regulators to verify the chronological entry of records.

4658.0465 TRANSFER, DISCHARGE, AND DEATH.

One aspect of the revision of the current rules is to cluster related topics to enable easier locating of rules which apply in certain situations. The rules relating to clinical records at the time of transfer, discharge and death are an example of that clustering. The current Chapter 4655 contains language very similar to both subparts found in 4658.0465, but in two separate parts. By re-organizing the applicable revisions to current rule parts, we have attempted to make these proposed rules easier to use than the existing rules.

Subpart 1: It is necessary to require a discharge summary for each resident in order to complete the clinical record with the outcome of the stay in that nursing home. This is a current requirement (found at Part 4655.3300, subpart 2), and is a part of the standards of practice of the clinical records professionals. The language being proposed is reasonable because it is not significantly different from the current language which has not been found to be problematic.

Subpart 2: It is necessary to require pertinent resident information to accompany a resident being transferred to another care facility to assure continuity of care for that resident. The pertinent information from the clinical record will indicate to the admitting facility what cares, treatments, medications, and other services the resident needs and has been receiving so that the resident can continue to receive appropriate care, thus assuring the continued health, safety, comfort, and well-being of that resident. The language being proposed clarifies the intent of the current rule found at Part 4655.3500, subpart 4.

4658.0490 PENALTIES FOR CLINICAL RECORDS.

See the discussion in part 4658.0045, above. Many parts of this section of proposed rules are not significantly different from current rule language. The proposed fines for noncompliance with those sections are the same as for the comparable sections in the current rules. This includes parts 4658.0445, 4658.0450, 4658.0455, 4658.0460, 4658.0465, and 4658.0470.

The fines for noncompliance with correction orders for parts 4658.0430, 4658.0435, 4658.0440, and 4658.0475 have been established in accordance with the 8 tier level of fines developed to correlate with the impact of noncompliance on the resident.

Part 4658.0430 describes the maintenance of a health information management service, the quality of that information, and a person responsible for health information management. The proposed fine for noncompliance with this part is set at $300, the penalty assessment for rules that are necessary to ensure that services are properly provided. This amount is reasonable because noncompliance with these rule parts would affect the quality of care that is provided to the residents. These rules are directly related to the actual provision of health information management services, or in other words, the maintenance of clinical records. Compliance with these rules is necessary to assure that the actual provision of health information management services is done in a safe and effective manner. Noncompliance with these rules would result in the inability to adequately meet the needs of the residents. The importance of assuring that the mandated services are provided justifies the imposition of the $300 penalty assessment.

Part 4658.0435 addresses the confidentiality of the clinical records, both in storage and if information is received or transmitted electronically. The proposed penalty assessment for noncompliance with this part is $250. This level of fines is assigned to those rules that related to the protection of the individual rights of residents. A violation of one of these parts could jeopardize the well-being of residents and could also jeopardize the resident's health. The rules are necessary to assure that the residents' rights to privacy and the right to adequate and considerate care are fully protected. The $250 level of penalty assessment is appropriate for noncompliance with the proposed part 4658.0435.

Part 4658.0440 requires an explanation key for abbreviations or symbols used in documentation and data collection. The proposed penalty assessment for noncompliance with this part is $50. This level of penalty assessment is assigned to those rules that do not directly jeopardize the health, safety, treatment, comfort, or well-being of residents. The existence of an explanation key is a required minimum standard necessary to promote the proper operation of the nursing home, but the potential for harm presented to residents as a result of noncompliance is not direct.

Part 4658.0475 describes the minimum requirements for an electronic, paperless health information management system. If a nursing home chooses to use an electronic system, it would be the nursing home's health information management service, and as such would need to be established properly to ensure that the services are properly provided. The proposed level of penalty assessment for noncompliance with this part is $300. This level of fine is consistent with those for other rules which address the appropriate operation of the health information management service and maintaining confidentiality of resident information.

NURSING SERVICES

4658.0500 DIRECTOR OF NURSING SERVICES.

The language proposed in part 4658.0500 is a revision to the current rule language found in part 4655.5700. This part describes the need for a director of nursing service and the requirements of that position. It is necessary to specify in rule that each nursing home have a director of the nursing service to assure that each facility will be providing appropriate nursing care under the direction of a registered nurse who is employed full-time at that nursing home and who is educated appropriately for their role. These requirements are reasonable since residents are admitted to the nursing home needing nursing care and there must be someone responsible for the provision of this care.

The proposed part 4658.0500, subpart 1 contains the same language as the current part 4655.5700, subpart 2.

The proposed part 4658.0500, subpart 2 is a revision of the current part 4655.5700 subpart 3. The proposed language deletes the requirement that the director of the nursing service be employed full-time "during the day shift (between 7 a.m. and 7 p.m.)". This proposed deletion is needed to make the rule more compatible with the federal OBRA 87 language. It is important that the director of nursing service is aware of resident care given in the facility. This proposed deletion would give the director of nursing service the flexibility to work any shift as needed, and so would provide a way for monitoring the evening and night shifts, if that is most appropriate for that nursing home. The flexibility would allow directors of nursing service to change their scheduled shift as necessary. It is reasonable to allow this sort of flexibility so that nursing homes can staff most appropriately for the needs of their residents.

The proposed part 4658.0500, subpart 3 revises the current part 4655.5700 subpart 4 by deleting the term "her" and making the language non-gender specific. The rule language would remain because it is necessary that someone be assigned and available to assist the director of nursing services in carrying out the director's duties 7 days a week or to take the director's place in any absence. The title of this person does not have to be "assistant to the director", but would need to serve as an assistant to the director. The title may vary depending on nursing home preference and practice. The essential thing is that there be one (or more) licensed nurse designated to provide assistance to the director of nursing service to provide continuity of resident care.

The proposed subpart 4 is a revision to the current part 4655.5700 subpart 5. It contains new language developed in response to comments from workgroup members providing suggestions for revisions to the rule language. This proposed language incorporates additional areas of education as a requirement for director of nursing service training. The additional areas of education are necessary and reasonable to incorporate in rule because they represent a large portion of the duties and responsibilities performed by directors of nursing service. There is a very high turnover rate in directors of nursing services positions, often because those persons are overwhelmed by the responsibility inherent in the position. By requiring training in all areas that directors of nursing service will likely encounter, it can be expected that they would be

better prepared for their positions; by being better prepared, they will likely remain longer and fulfill their duties in a more effective manner. Directors of nursing service would have the knowledge for expected responsibilities and the expertise to meet the responsibilities. All proposed areas of training hold equal importance and therefore training in all the listed areas would be required. The requirement for having this education completed "prior to or within the first 12 months after appointment as director of nursing service" is reasonable because it allows for someone who is otherwise qualified for this position to obtain additional training if it has not already been attained, while serving in that position.

The proposed training requirements could likely be met at the same time the nurse is fulfilling the nurse licensure requirements for continuing education. Provider organizations offer much of the required training to their member facilities. For example, Care Providers of Minnesota sponsors an annual DON Institute, which is a two-day session for directors of nursing services, and offers other training programs throughout the year, which generally cost $75 to $195, depending on the training program. The Minnesota Association of Homes for the Aging (MAHA) offers a program which generally runs 3 days, and is offered in four phases, with each phase costing $75 to $100, depending on the program. There are other training programs available through private companies, one of which is a three-day session and costs $375. And the University of Minnesota School of Public Health offers a program in "Patient Care Administration;" this program lasts two years for a credentialing / certificate, and three years for a Masters degree. For the 1993-1994 school year, costs for that program are approximately $2,520 for each of the first two years (approximately 15 credits per year), and around $2,720 for the third year (approximately 25 credits).

While there may be increased costs associated with these revised training requirements, there will likely be some cost savings associated with a lower turnover rate. One nursing home administrator estimated that the costs associated with hiring and training in a new director of nursing often run to at least one-third of the annual salary of the director of nursing. If the director of nursing services makes $12 per hour, and is paid for 2088 hours per year, one-third of that would be over $8,300. By lowering that turnover rate, the hiring and training costs could be decreased.

The Department proposes that the grandfathering of the incumbent directors of nursing services takes place when these proposed rules are adopted, to ensure that current directors of nursing service may maintain their positions. In other words, this proposed requirement for training within 12 months of appointment as director of nursing services will not apply to those persons currently serving as directors of nursing services at licensed nursing homes, as long as they remain in that position at that nursing home. Incumbent directors of nursing who have been grandfathered in at one nursing home, and then later accept a director of nursing services position at a different nursing home, will be required to have completed all proposed areas of education within 12 months after appointment as director of nursing services at the second nursing home.

4658.0505 DIRECTOR OF NURSING SERVICE; RESPONSIBILITIES.

The proposed part 4658.0505 is a revision to the current part 4655.5800, addressing the responsibilities of the director of nursing service.

The proposed part 4658.0505, a revision to the current 4655.5800 subpart 2, would require the nursing home to specify the responsibilities of the director of nursing service in a job description. This proposed revision to the rule would allow the administrator and the director of nursing service to know exactly what duties the director of nursing is responsible for at that individual nursing home. There are few changes to the current rule language within the items that the director of nursing service is responsible for. The main difference between current rule and the proposed rule is the proposed requirement that these responsibilities be included in a job description (rather than the current requirement merely that these are the items the director of nursing service is responsible for).

The proposed item A contains a grammatical change from the current rule, updating the term "patient" to "resident."

The proposed item B also includes primarily grammatical changes. The term "and implementing" was added to the rule to assure that nursing procedures are carried out, not just established. This proposed revision is necessary to make the regulation stronger by requiring the director of nursing service to carry out the expected responsibilities, not just writing down policies and procedures.

The proposed item C discusses the orientation program for new nursing personnel and continuing education for all staff. By not including the last sentence from the current part 4655.5800, subpart 2, item C (which states when there must be an inservice director other than the director of nursing service), nursing homes would be allowed more creativity in determining the amount of administrative nursing staff that is needed. It then becomes a more outcome oriented task to ascertain if the director of nursing service duties regarding staff orientation and training have been adequately carried out.

There was much discussion among workgroup members regarding the intent of the proposed item D. That discussion dealt with attempting to include a term in the rule to best describe the responsibility of the director of nursing service regarding staffing levels and the interaction with the administrator on setting those staffing levels. Staffing levels are often tied to reimbursement as well as residents' needs, which can cause problems or difficulties in some circumstances. Changing the term from "recommending" in the current part 4655.5800 subpart 2, item D to "determining" with the administrator gives strength to the director of nursing service recommendations and input to the necessary nursing personnel staffing levels.

Proposed item E contains the same language as the current part 4655.5800, subpart 2, item E.

The proposed item F revises the current 4655.5800 subpart 2, item F by adding language. This addition is necessary because it clarifies the authority of the director of nursing service to perform necessary duties related to delegation of responsibilities of other nursing personnel. The

language would be added to the rule for convenience of the nursing home staff, because the relevant references to regulations may not be readily available to all nursing home staff. This proposed language is reasonable because it is consistent with other state regulations dealing with nurse delegation of tasks.

The proposed item G contains a grammatical change from the current part 4655.5800, subpart 2, item G, updating the term "patient" to "resident."

The proposed item H is a revision of the current part 4655.5800 subpart 2, item H. The current rule language referring to the "patient care plan" actually requires a minimum of a 30 day review of the "nursing care plan" rather than the entire resident plan of care. Proposed language is necessary and reasonable because it is patterned after federal requirements for reviewing resident assessments at least every 90 days and at the time of a permanent or significant change.

The proposed item I contains a grammatical change from the current rule, updating the term "patient" to "resident."

The proposed item J contains identical language to the current 4655.5800, subpart 2, item J.

The current part 4655.5800, subpart 2, item K language requires nursing personnel to accompany physicians when residents are seen by the physician. The proposed amended language is more reasonable, since it allows for physicians to visit residents without the presence of nursing staff. This allows residents, opportunity for privacy during their physician's visits. It permits nursing staff and the physician to communicate as necessary to plan resident care while affording privacy for the resident. The proposed language is not intended to prohibit the director of nursing services or other nursing staff from accompanying a physician on their rounds. Rather, the proposed language is necessary and reasonable because it allows greater flexibility for the facility staff as well as encouraging residents' privacy rights.

There were no changes to the proposed item L from the current part 4655.5800, subpart 2, item L.

The proposed item M contains a grammatical change from the current part 4655.5800, subpart 2, item M, updating the term "patient" to "resident."

4658.0510 NURSING STAFF.

The proposed part 4658.0510 is a revision to the current parts 4655.5600 and 4655.5800 dealing with nursing staff requirements.

The current part 4655.5600, subpart 2 would be revised by deleting the terms "nurse aides" and "orderlies". These terms are outdated; the proposed language reflects a more universally accepted term, and matches federal certification terminology. Another proposed change in this subpart would be deleting the reference to a past date when the regulation requiring a minimum

number of nursing hours became effective. It is no longer relevant to include this date in the rule. The important issue to this subpart is that a minimum number of nursing hours are required. There needs to be a basic standard for the amount of nursing services provided and this is provided by the statute and this proposed rule. The requirements are for a minimum of 2 hours of nursing personnel per resident per 24 hours, and a minimum of 0.95 hours of nursing staff per standardized resident day, plus additional nursing personnel to meet the needs of the residents. Minnesota has a case mix reimbursement system, with each resident in a certified nursing home being assigned a case mix classification based on their level of care needs. A "standardized resident day" is defined in the statute as the sum of the number of residents in each case mix class multiplied by the case mix weight for that resident class, calculated on the basis of a facility's census for any given day. These case mix classifications and weights are described in Minnesota Rules, Chapter 9549.

Changes in nursing home populations are changing the market and supply and demand, causing nursing homes to provide higher levels of care. The majority of nursing homes do meet this requirement for minimum nursing staff levels (which is also mandated by Minnesota Statutes, §144A.04, subdivision 7). The requirement for minimum number of nursing hours is needed in rule to provide protection for residents, and an assurance that they will be receiving some minimum level of nursing care while residing in the facility. The minimum requirements for 2.0 hours per day, .95 hours of nursing personnel per standardized resident day, and additional staff as needed to meet resident are both included in the proposed rule for purposes of staff education and convenience, because the statutory requirements may not be readily accessible to staff in the nursing home, and those staff do need to be aware of these minimum requirements.

The proposed rule language does not exempt the nursing home from also having sufficient numbers of staff on duty to meet the nursing needs of the residents, which is also included in this rule part. Rather, this formula is a basis from which the number of nursing hours provided can be determined. Minimum standards for nursing hours also help nursing homes meet federal regulations, and justify expenditures on cost reports for nursing personnel. It is possible for nursing homes to meet the 2.0 minimum of nursing hours per day per resident, but not meet the federal requirements for "sufficient" staff. If there were no minimum, it is likely that some nursing homes would not provide adequate nursing care. When staffing is at or below these requirements, both residents and staff suffer. "Sufficient number of qualified nursing personnel" would also remain in the state rule. This terminology is necessary and reasonable because it ensures that nursing staffing levels must meet resident needs. This would include having staffing levels over 2.0 hours per day per resident if needed for resident care.

The proposed language for 4658.0510, subpart 2, is a revision to the current 4655.0100, subpart 8, item E. Current language requiring a "registered nurse or a licensed practical nurse" is replaced with "a licensed nurse" in the proposed language because the language is more up to date and includes both registered nurses and licensed practical nurses. The current requirement for having registered nurses and licensed practical nurses "during the day shift" has been deleted. This gives the nursing home the flexibility to determine when these nursing positions best meet the needs of the residents.

Proposed subpart 3 contains the same language as current part 4655.0100, subpart 8, item F.

The proposed part 4658.0510, subpart 4 (formerly part 4655.5800, subpart 3) would be renumbered to correspond with the other parts of this proposed section.

There is a proposed revision to the last sentence in the current part 4655.5600, subpart 2, which is included in this proposed part 4658.0510, subpart 5. This proposed revision is a grammatical change from the term "be used to give" to the term "provide." This revision is necessary to clarify the intent of this part -that non-nursing staff does not perform nursing duties. This revision is reasonable because it provides for an easier to understand term to be included in the rules. Nursing duties would include but not be limited to duties as stated in proposed rules 4658.0520 and 4658.0525.

4658.0515 FREQUENCY OF REPORTING.

The proposed part 4658.0515 is a revision to the current part 4655.3900, subpart 4. The first three subparts of the current 4655.3900 would be included with the proposed rule parts dealing with clinical records, administration/operations, or pharmacy services. This revision is intended to organize the rules into a grouping where the rules dealing with specific areas would be located together.

The first sentence of the current part 4655.3900, subpart 4 is proposed to remain with the rule parts dealing with nursing services because it is appropriate in this location. A grammatical change is proposed, changing the term "nurses' notes" to "nursing notes." A second grammatical change is proposed, changing the requirement for nursing notes to be recorded "weekly" to nursing notes must be recorded "every seven days" because it clarifies the frequency of expected documentation. The second sentence of current subpart 4 is now included in the clinical record portion of these proposed rules.

4658.0520 ADEQUATE CARE.

The proposed part 4658.0520, subpart 1 contains a grammatical change from the current part 4655.6400, subpart 1, updating the term "patient" to "resident."

The proposed 4658.0520, subpart 2, item A, contains the same language as the current part 4655.6400, subpart 2, item A.

The proposed 4658.0520, subpart 2, item B, is a revision of the current 4655.6400, subpart 2, item B. The proposed language deletes the requirement for a weekly bath for residents. It contains new language which would allow the nursing home staff to determine the appropriate bathing schedules for residents based on resident needs and make this determination a part of the resident's care plan. The proposed language is also necessary to allow for resident choice in determining a bathing schedule which would also give the nursing home more flexibility when planning resident care. Additional proposed language is patterned after current part 4655.6800, item A. It is reasonable to include this language specifying that incontinent residents be checked every 2 hours and have perineal care done because it will decrease the risk of skin breakdown.

Specificity is included in this proposed rule to assure that resident skin is kept clean and dry

which will also help to decrease skin breakdown. Without this specificity, it is possible that some facilities would not provide these cares. A definition of perineal care is included in the proposed language to clarify for nursing home staff what steps must be taken for the resident after every incontinent episode.

The proposed 4658.0520, subpart 2, item C is a revision of the current part 4655.6400, subpart 2, item C. Proposed language deletes the requirement for "monthly" shampoos and is made more stringent by requiring shampoos every 7 days. It is reasonable to make this proposed part more stringent because it is meant to provide resident comfort and self-esteem. The proposed language is only a minimum requirement. Facilities would still need to shampoo residents' hair more frequently than every 7 days if needed. Without a specific requirement, some facilities would fail to provide this care. "Seven days" also clarifies the current requirement for weekly and makes the proposed rule easier to enforce.

The proposed subpart 2, item D revises the current part 4655.6400, subpart 2, item D by deleting the term "men patients or" and making the language non-gender specific. The language would remain because it is necessary to assure a particular aspect of care.

The proposed part 4658.0520, subpart 2, item E contains the same language as the current part 4655.6400, subpart 2, item E.

The proposed part 4658.0520, subpart 2, item F contains the same language as the current part 4655.6400, subpart 2, item F.

The proposed part 4658.0520, subpart 2, item G contains the same language as the current part 4655.6400, subpart 2, item G.

The proposed part 4658.0520, subpart 2, item H contains a grammatical change from the current part 4655.6400, subpart 2, item H, updating the term "patient" to "resident".

The proposed part 4658.0520, subpart 2, item I is a revision of the current part 4655.3900, subpart 2. The proposed language deletes the requirement for doing the temperature, pulse, respirations, and blood pressure (T,P,R and BP) every 4 hours for the first 24 hours. This change is necessary because the burden of when to monitor a resident's T,P,R and BP is on the facility. This is important because the resident's condition will indicate how often the monitoring will need to be done. This could be more or less frequent than every 4 hours. The proposed rule also deletes the current requirement for "pertinent observations". The proposed Clinical Record rules contain language requiring pertinent factors regarding changes in the resident's general condition to be in the clinical record and it is more appropriate to include it in that part of these rules. The current requirement for "weekly" has been changed to "seven days" for clarification and enforcement purposes.

The proposed part 4658.0520, subpart 2, item J is a revision to current 4655.3900, subpart 2. Instead of requiring "weight" only, the proposed language adds "height" to the requirement. This proposed language is necessary and reasonable because weight alone will not give an accurate assessment of the resident. By requiring facilities to record both the height and weight,

a more accurate assessment of the resident's needs will be determined. The current requirement for weights to be measured monthly has been changed to every 30 days for clarification and enforcement purposes.

4658.0525 REHABILITATION NURSING CARE.

The proposed part 4658.0525 is a revision to the current part 4655.5900, dealing with rehabilitation nursing care. Language throughout the current part 4655.5900 and the proposed part 4658.0525 is consistent with the federal certification language. The proposed revisions are necessary and reasonable because they would strengthen the coordination of federal and state regulatory language.

Language in the proposed part 4658.0525, subpart 1 is a revision to the current rule language in part 4655.5900, subpart 2, item A. The revisions are taken directly from the federal certification requirements, and are incorporated into this state rule to strengthen the language regarding attainment of positive resident outcomes. Current rule language requires a resident to achieve the highest level of self-care and independence as recorded in the "patient care plan", which is also known as the "nursing care plan". This "nursing care plan" does not include a comprehensive assessment of the resident, and only requires the resident to achieve and maintain their highest level of self-care and independence. There are many additional aspects of resident well-being that need to be addressed in a comprehensive or even adequate care plan. The proposed language is necessary and reasonable because it captures all aspects of resident care. It incorporates the achievement of the "highest practicable physical, mental, and psychosocial well-being" relating to rehabilitative nursing care with that level of achievement from all disciplines or services.

The proposed language is necessary because it expects that each aspect of the resident's care be reviewed and that resident needs be addressed. "Highest practicable" is the highest level of functioning and well-being possible, limited only by the individual's presenting functional status and potential for improvement or a reduced rate of functional decline. Care and services for the resident to attain the highest practicable well-being must be provided to each resident. "Highest practicable" can be determined through the results of a comprehensive resident assessment, addressing the physical, mental, and psychosocial needs of the individual resident. The proposed language is reasonable because it requires the nursing home to ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

The proposed part 4658.0525, subpart 2 is a revision to the current part 4655.5900, subpart 2, item B. The current rule language is less specific than that used in the federal certification language. The language in the proposed part 4658.0525, subpart 2, items A and B, follows the federal regulatory language, and forces nursing homes to be more responsible, responsive, and outcome oriented in terms of residents' range of motion. The specificity in the proposed language is necessary because it makes the regulation's expected outcome clearer and easier to understand and to enforce. The proposed rule part details the expected outcomes to or for the residents. This rule part is necessary to assure that, based on the resident assessment, residents who enter a nursing home do not experience a deterioration in their range of motion (ROM)

unless it was unavoidable and adequate preventive care was provided. The proposed rule is reasonable because it assures that a resident entering the nursing home with a limited range of motion receives adequate preventive care consistent with the resident's comprehensive assessment and care plan. This may include active ROM performed by the resident; passive ROM performed by staff; active-assistive ROM exercise performed by the resident and staff; and application of splints and braces if necessary.

The proposed part 4658.0525, subpart 3 includes portions of the intent of the current part 4655.5900, subpart 3, dealing with skin care of residents. The proposed language incorporates federal regulatory language addressing the care and prevention of pressure sores. Again, items A and B in this proposed subpart are necessary and reasonable because they rely on the comprehensive assessment of the resident to determine whether the resident entered the nursing home with pressure sores, and so should not be developing them once in the nursing home, or whether the resident entered the nursing home with pressure sores and so requires necessary treatment and services for them. Although there may be certain cases when pressure sores may be clinically difficult to prevent, a determination that development of a pressure sore was unavoidable may be made only if routine preventive and daily care was provided. This would include but not be limited to turning and proper positioning, application of pressure reduction or relief devices, providing good skin care, providing clean and dry bed linens, and maintaining adequate nutrition.

The proposed part 4658.0525, subpart 4, item A, a revision of the current 4655.5900, subpart 3, item A, addresses positioning. It specifies that residents must be positioned in good body alignment. It is necessary and reasonable to require this rule because proper positioning can be a preventive means to decrease the risk of developing pressure areas and can assist in the healing process of pressure sores, as well as preventing contractures or minimizing the risk of further contractures. It would therefore add to the quality of life for residents.

The proposed part 4658.0525, item B is a revision of the current 4655.5900, subpart 3, item B. The proposed language deletes the requirement for encouraging and assisting "bedfast" residents to change positions at least every 2 hours, day and night. This proposed deletion is necessary because the current rule only addresses bedfast residents. It is reasonable and necessary to require that all residents who are incapable of changing their own position be repositioned at least every 2 hours to avoid problems such as those described above.

The proposed part 4658.0525, subpart 5 is a revision to the current part 4655.5900, subpart 2, item C. The current language does not assure the attainment of a positive resident outcome regarding bowel and bladder training programs. Proposed language follows the federal certification principles. Proposed language is reasonable and necessary because it is written in an easier to understand manner, and requires that cares be given based on the resident's comprehensive assessment of their needs, abilities, and health status.

The proposed part 4658.0525, subpart 5, item A is necessary because it would assure that residents are not catheterized for staff convenience but only if there is valid medical justification. It is the responsibility of the nursing home to show evidence of any medical factors which may cause or lead to catheterization. Generally, chronic, indwelling catheter use should occur only

after a restorative program to improve bladder function has been attempted and/or nursing home staff have tried to manage the incontinence in some other way. The proposed item B is reasonable because it would assure that the resident is provided treatment and services based on the type, severity, and cause (if known) of the urinary incontinence, and there is an attempt made to restore normal bladder functioning.

The current language found in part 4655.5900, subpart 2, item D would be deleted under these proposed revisions because it is not specific enough and does not address the rehabilitative nursing cares being provided in nursing homes today. The proposed language in part 4658.0525, subpart 6 comes from federal certification language, and is reasonable because it is more specific and easier to understand. The proposed language requires that care and services in the activities of daily living (ADLs) must be provided to each resident. Appropriate treatment and services include all cares provided to residents, whether by employees, contractors, or volunteers of the nursing home, to maximize the individual's functional abilities. The proposed language is necessary because the nursing home would be required to ensure that a resident's abilities in ADLs do not deteriorate unless the deterioration was unavoidable. Also, the nursing home would be required to provide the appropriate treatment and services to maintain or improve residents' abilities to perform ADLs. Those residents unable to carry out ADLs would receive the services necessary to maintain good nutrition, grooming, and personal and oral hygiene.

The proposed subpart 7, items A and B would be new language in these state licensing rules. It is patterned after federal certification language, with the addition of a reference to feeding syringes. While some health conditions demonstrate that nourishment via a naso-gastric tube or feeding syringe is unavoidable, this proposed rule is necessary because it limits the use of tube feedings or feeding syringes, especially those ordered for the convenience of the nursing home, and requires that residents fed by tubes or syringes receive appropriate care and treatment to prevent problems from occurring as a result of the use of that tube or feeding syringe. Again, the comprehensive resident assessment is a vital part of the determination of the cares and services appropriate for each individual resident.

The proposed part 4658.0525, subpart 8 is a revision to the current part 4655.5900, subpart 3, item F and the final paragraph in that subpart. There are minor grammatical changes proposed to the current rule language from item F. In addition, the last paragraph of the rule part would not be included in proposed language because it is too restrictive. This proposed rule is reasonable because nursing homes should be able to provide training for rehabilitative nursing by methods of their choice, and appropriate to the needs of their staff and residents. There are enough options available to nursing homes to find appropriate staff training, that the Health Department no longer needs to specify in rule where to get a certain nursing manual.

Proposed subpart 9 is a revision to the current part 4655.6800, item C. The proposed language corresponds with the federal certification language while retaining specificity from the current state language. The current rule language requires water and other fluids to be available at the resident's bedside. The proposed language would require that residents are offered and actually receive adequate water and fluids to maintain their proper hydration and health. They would receive adequate fluids regardless of whether at the bedside or somewhere else in the nursing

home. It is necessary to clarify the intent of this rule to provide greater protection for residents, and assurance that they will remain properly hydrated. The proposed language is reasonable because it allows great latitude to the nursing home to meet the resident's hydration needs, while including the provision for those residents who need to have their fluids restricted.

Proposed subpart 10 is a revision of the current part 4655.5800, subpart 2, item C and 4655.5900, subpart 3. The proposed language specifies that there should be continuous in-service training in rehabilitation for all nursing personnel. This provision is necessary and reasonable to assure that staff are able to competently apply the interventions necessary to meet the resident needs and maintain the residents' highest practicable level of functioning or well-being.

4658.0530 ASSISTANCE WITH EATING.

Subpart 1: This proposed rule part, a revision to the current language found in 4655.6100, is necessary to clarify that it is the responsibility of nursing personnel to ensure that residents receive the diets prescribed by their physician, and that resident rights are maintained and promoted in the methods of feeding the residents. The language is reasonable because it provides clear statements of the expectations for assistance with eating.

Subpart 2: Language addressing the use of volunteers or other nursing home staff to assist residents with eating is proposed in part 4658.0530, subpart 2. The proposed language is based on current policy and standards of practice. It is necessary to specify in rule the conditions to be met if persons other than nursing personnel assist residents with eating in order to protect the health, safety, comfort, and well-being of residents. The language being proposed is reasonable because it states the conditions in easy to understand text, and those conditions are based on standards currently in use that nursing homes are familiar with and are readily able to comply with.

4658.0580 PENALTIES FOR NURSING SERVICES.

See the discussion in part 4658.0045, above. This section of proposed rules is not significantly different from current rule language. The proposed fines for noncompliance with those sections are the same as those for the comparable sections in the current rules.

MEDICAL DIRECTOR

Part 4658.0700 MEDICAL DIRECTOR.

The proposed rule language to the state licensing rules for nursing homes specifies that each nursing home must have a medical director, and delineates the role and responsibilities of that medical director. It is necessary and reasonable to require a medical director because it allows a sharing of responsibility for assuring the facility is providing appropriate care as necessary. This new requirement is intended to enhance the care and treatment being provided to the nursing home residents. The federal certification regulations require each certified nursing facility to designate a physician to serve as medical director. That medical director is responsible for implementation of resident care policies and the coordination of medical care in the facility. Since this is a new requirement for the state licensing rules, these proposed state requirements specify what is expected of the medical director in greater detail than do those federal regulations. Currently, there are 8 "licensed only" nursing homes listed in Minnesota which are not federally certified to participate in the Medicare or Medicaid programs. One of these has already applied for participation in Medicare; one is a Christian Scientist home and does not operate on a medical basis; another uses its own physicians to do tasks similar to that of a medical director; one has a physician on the Board of Directors on a pro bono basis who has helped with policies and felt that having a medical director was a good idea; three currently contract for or consult with medical directors; and one had a medical director who recently retired and the nursing home is in the process of finding another. In view of this information, requiring a medical director should not pose a hardship on these non-certified nursing homes.

Subpart 1 Designation: We are proposing that the nursing home designate a physician to serve as the medical director. It is reasonable to omit a specific amount of time needing to be spent by a medical director because we felt the primary issue was to require that this service meet the resident needs. It becomes the nursing home's responsibility to assure that these needs are met and to allocate the medical director's time appropriately.

Subpart 2 Duties: The medical director has a coordinating role and shares responsibility for assuring that the nursing home is providing appropriate medical and nursing care as required by residents. This includes developing, monitoring, and implementing resident care policies, as well as providing direction and supervision of physician services and the medical care of residents. "The medical director of a nursing home can have substantial impact on the quality of care, and hence the quality of life, of residents. The position has both clinical *and* administrative components."[9]

Developing standards for physicians would include but not be limited to performing histories and physical examinations ("physicals"), making timely visits to residents, signing orders, responding to pharmacy drug reviews, diagnosing residents, assisting with the development of comprehensive resident care plans, and writing progress notes. The proposed rule also includes

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[9] Levenson, S., "The Changing Role of the Nursing Home Medical Director," Long Term Care Currents, Ross Laboratories, Vol. 14, No. 2, 1991.

a role in overseeing the overall clinical care of residents to ensure that care is adequate to the best extent possible. It is necessary and reasonable to list responsibilities in the proposed language to clarify medical directors' duties which include evaluating situations and taking appropriate steps to correct the problem when there is a concern about inadequate or inappropriate care. This action could include consultation with the resident, the resident's family and/or the resident's physician concerning care and treatment. Surveillance of the health status of employees helps to assure that employees do not bring diseases or illness to vulnerable residents. The proposed language regarding medical director participation in the quality assurance meetings was added because the medical director's overall responsibilities would provide information necessary to assist in providing quality care. The "duties" in the proposed rules were obtained from previous federal certification rules and from recommendations in The Report of the Commissioner's Task Force on Nursing Home Mortality Review.[10]

MEDICAL SERVICES

Part 4658.0705 MEDICAL CARE AND TREATMENT.

Subpart 1 Physician Supervision: There are some grammatical changes to rule language currently found in 4655.4600 Subpart 1 proposed in this subpart to eliminate gender references and to use current terms. The final sentence from the current part 4655.4600, subpart 1 is being eliminated because it is unnecessary to specify in rule that the resident's attending physician reside in the same or nearby community. When these rules were originally written that may have been a reasonable standard. At this time it is necessary and more reasonable to require that the resident receive appropriate medical care and medical supervision of their care and treatment than in specifying where the physician must reside.

Subpart 2 Availability of physicians for emergency and advisory care: The intent of this subpart has not changed with the proposed language being added to language currently found at 4655.4600, subpart 2. The state rule language is being matched more closely with the federal certification language. The requirements for nursing homes in terms of having an agreement for emergency physician services are being made more specific. The intent of the current 4655.4600, subpart 3 has been incorporated into this subpart with the inclusion of the last sentence, which requires that the name and telephone number of the emergency physician (or physicians) be readily available for facility staff in the event the facility needs to contact a physician. It is necessary to require a time period in this subpart to ensure that emergency problems are evaluated within a reasonable timeframe.

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[10] "Commissioner's Task Force on Nursing Home Mortality Review Report," Minnesota Department of Health, November 1990.

Part 4658.0710 ADMISSION ORDERS AND PHYSICAL EVALUATIONS.

Subpart 1 Physical examination at admission: The addition of "physician assistant" and "nurse practitioner" was made to current language to make it compatible with other state laws and rules, and to address current practices. The current state regulation at part 4655.4700 requires the history and physical to be completed within five days prior to admission or within 72 hours after admission.

The time period for the history and physical would be changed from 72 hours to seven days after admission because it is a more realistic time period in which to have the history and physical done. It is necessary for the nursing home to have current information to assure that nursing staff is fully apprised of the resident's condition and to provide appropriate cares. Specific time frames are necessary and reasonable to protect the health and safety of the residents. The time period currently specified in rule for preparing a comprehensive plan of care could interfere with the care of the resident. Frequently, residents are admitted to the nursing home directly from a hospital, and hospital discharge summaries do not always accompany the resident on admission to the nursing home. Other admissions come from "home" and therefore do not always have this information available. The current and proposed language for doing a history and physical within five days prior to admission does not preclude a nursing home from using a current discharge summary as long as it was completed within five days prior to admission. Any discharge summary completed prior to five days before admission may be updated within the five days prior to admission or at least verified by the physician that the information is still current.

The portion relating to "medical records" currently found in 4655.4700, subpart 1, was not included in this section because it has been included in the proposed rules addressing clinical records.

Subpart 2 Admission orders: It is necessary to add this language to clarify the requirement for physician orders at the time of admission. Previous language in subpart 1 pertaining to admission orders was deleted. It is of critical importance that staff are aware of the immediate needs of a newly-admitted resident. A comprehensive resident assessment of the resident is required no later than 14 days after admission and the resident's comprehensive plan of care is not required until seven days after the completion of the comprehensive assessment. Because the comprehensive resident assessment must include medically defined conditions and prior medical history, physical and nutritional status, special treatments or procedures as well as other information, it is imperative that the nursing home have instructions relative to the immediate care of a resident at admission. The physician is the person who is in the position to provide this information.

Subpart 3 Frequency of physician evaluations: With these proposed revisions, the title of this Subpart would be changed from "periodic physical examination requirements" to "frequency of physician evaluations". This proposed change is reasonable because "examination" implies a hands-on review of the resident's physical function and system as opposed to "evaluation" which implies that the physician or the physician's designee sees and converses with the resident while not necessarily conducting a hands-on review. It is the responsibility of the physician or

physician designee to deter ine the type and extent of examination needed, if any, to evaluate the condition of the reside The proposed language is needed because it attempts to clarify the expectation. Item A is c tent with federal regulations except for the last four words "then whenever medically neces " The purpose of this proposed language is for economic reasons. Current rule language req es visits to be made at least every six months. The proposed language allows the time between physician visits to exceed six months if there is no reason that a resident be seen within that six months. This rule is reasonable because there should be decreased costs to residents and third-party payers if the resident no longer has to be examined every six months, whether or not that timeframe is medically indicated, but rather on an as-needed basis. Even though the current federal language states that visits must be "every 30 days for the first 90 days after admission and at least every 60 days thereafter" professional nursing judgement can determine if a visit is necessitated prior to this time period. Residents or their guardians, families, and physicians can also determine if a physician visit is needed at any given time. Consumer education would be an important factor regarding expectations of the physician and services received.

Item B is consistent with federal regulations and is updated to reflect Minnesota Law which allows "physician visits" to be made by a physician assistant or nurse practitioner. Duties appropriate for physician assistants are covered under rules addressing the scope of their practice at part 5600.2615. Prescribing authority appropriated to nurse practitioners is covered under Minnesota Statute 148.235, and other duties are covered under the Nurse Practice Act (Minnesota Statutes 148.171 to 148.285).

Subpart 4 Physician visits: The proposed rule is based on current federal certification language except for the addition of "progress notes" to item A. The intent of current rule language at 4655.4700 is to have physician progress notes at the time of every "examination" and to have signed orders. A "visit" does not necessarily mean that an "examination" be performed as stated in current rule. The title of this proposed rule is consistent with other proposed language pertaining to "visits" versus "examinations." The proposed rule is needed to clarify what the physician or physician designee must review during each "visit". Proposed language is also needed to make it easier for physicians or their designees to know what is expected of them when a "visit" to the resident is made. It is reasonable to require that the physician or physician designee review the resident's comprehensive plan of care, medications and progress notes to ensure knowledge of the resident's current condition so that appropriate care can be provided. Requiring the physician or physician designee to write progress notes at every "visit" is also necessary to ensure that nursing home staff are aware of information that may affect resident care. It is reasonable to require that orders and progress notes are signed and dated for legal purposes.

Part 4658.0715 MEDICAL INFORMATION FOR CLINICAL RECORD.

Most of the language in this proposed rule has remained the same as the current 4655.4700 Subpart 1, but was written as a list of items rather than in paragraph form, for ease in reading. The current requirements regarding mantoux testing, laboratory reports and physician orders were deleted from this rule section and have been included elsewhere in the proposed rules. The previous requirement for "extent or restriction of activity" was deleted and replaced by "orders

for rehabilitations" in item F. Items H and I contain new language. Item H requires the physician or designee to document any advance directives the resident or responsible person has discussed with them. Item J would be added as a means of communicating family contacts to the nursing home, to promote consistency in care.

Part 4658.0720 PROVIDING DAILY ORAL CARE.

Subpart 1 Daily Oral Care Plan: This subpart is being proposed for the state licensing rules for nursing homes because it is necessary to establish minimum standards for providing daily oral care for residents. These minimum standards are needed to ensure that basic oral care needs of the resident are met. This proposed rule establishes minimum standards of care by listing criteria to be followed as a basic guide for caregivers who deliver oral care to residents. The subpart is reasonable because it clarifies what the responsibilities of the nursing home are for daily oral cares, documentation, staff assistance to the residents, oral hygiene and care supplies to be provided by the nursing home, and interaction with the provider of dental care, whether a dentist, dental hygienist, or other dental practitioner. The nursing home may do more than what is stated in these proposed rules but must meet the proposed minimum criteria. The language being proposed is also reasonable because it outlines specific outcomes without mandating who among the nursing home staff is responsible for providing or assuring those outcomes, nor mandating how the nursing home assures the outcomes (it does not specify methods, policies, procedures, etc.).

The language used corresponds with the federal certification language regarding the provision of dental services and supplies. Under this proposed language, a nursing home is not required to provide specific brands or types of oral hygiene items, but it is required to provide the supplies and assistance necessary for the resident to carry out their daily oral health care plan. If a resident desires a special or particular brand or type of item, the nursing home is not obligated to provide that special or particular brand or type of item. In that situation, the nursing home may charge the resident the difference between the cost of the item they regularly stock or normally supply and the cost of the special or particular item desired.

These proposed nursing home responsibilities blend with the federal certification requirements under the Medicare and Medicaid programs. Under those requirements, facilities have obligations to provide oral care supplies and assistance as part of the regular plan of care for each resident. The American Dental Association has developed a "Statement on Dental Care in Nursing Homes" (1991) which addresses the role of the dentist, a recommended dental care program for nursing homes, and suggestions for oral health education for residents and nursing home staff.[11] The proposed language incorporates the intent of those policies developed by the American Dental Association.

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[11] "Statement on Dental Care in Nursing Homes," American Dental Association Current Policies Adopted 1954 - 1991, American Dental Association, no. 1991:619: p. 104.

These daily oral cares are generally already being provided to all nursing home residents; the oral hygiene supplies listed are currently covered by Minnesota's Medical Assistance (MA) program. Therefore, there should be negligible effect to the nursing homes by proposing this subpart to the state nursing home licensing rules and adding clarification of the responsibilities of those nursing homes.

Subpart 2 Labeling dentures: The current state licensing rule (4655.4800, subpart 6) requires that nursing homes establish a procedure for the accurate identification of residents' dentures. The proposed language specifies that the nursing home must label the dentures within seven days of admission. Loss or misplacement of dentures is a common occurrence in many nursing homes. By setting a time period during which the dentures are to be labeled after admission, the intent is to reduce the chances for loss or misplacement of dentures, which can be a costly and time-consuming item to have replaced and which can have implications to the health and well-being of residents. It is reasonable to establish a time frame of seven days after admission for nursing homes to label dentures. This practice would be beneficial to the nursing homes in terms of staff time and resources spent determining whose dentures have been found. It is also a good practice in terms of customer service - providing a measure of security for residents' property.

4658.0725 PROVIDING ROUTINE AND EMERGENCY ORAL HEALTH SERVICES.

Subpart 1 Routine Dental Services: The proposed language specifies that the nursing home is responsible for providing or arranging for routine dental services to meet the needs of each resident. It spells out what would be included in "routine dental services." All the services listed are covered by the MA program (however, some of the services may require prior authorization by the Department of Human Services), as well as being covered by many insurance programs (again, some programs may have certain stipulations). This is no different than what is covered under those health insurance programs for persons not residing in nursing homes.

Subpart 2 Annual Dental Visit: The proposed language would require nursing homes to provide each resident with the opportunity for an annual visit to a dentist. This proposed rule is necessary to assure the resident care that meets community standards. As with any type of treatment or service, the resident always has the right to accept or refuse care from a dentist. However, the nursing home must provide the resident with at least the opportunity for a dental visit once a year. This entails asking the resident if they want to see a dentist and providing any necessary help to make a dental appointment. The language being proposed states that the initial dental visit referral after admission to the nursing home must be done within 90 days after admission, "unless the resident has received a dental examination within the six months prior to admission." The proposed language is reasonable because the allowance of up to 90 days post-admission for setting up the appointment allows the nursing home time to establish and maintain a daily oral health care plan, and ties into the quarterly care planning and assessment process.

Following the initial dental examination the nursing home would be required to provide opportunities for periodic dental checkups at least annually. It is reasonable to expect the nursing

home to present to the residents the opportunity for a dental visit once a year because this is the generally accepted standard for dental visits for most persons. The last sentence has been added for clarification purposes.

Subpart 3 Emergency Dental Services: The proposed language in item A corresponds with the federal certification language. Proposed item B expands on that federal language. The specification for contacting a dentist within 24 hours after the emergency dental problem arises would be a revision to the current state rules. It is necessary to include this specification in the proposed subpart to clarify the responsibilities of the nursing home, and it is reasonable to set this standard for a time period during which the nursing home should be contacting the dentist because it assures that emergency problems are evaluated within a reasonable timeframe. This is not a requirement that the nursing home resident must be seen by the dentist within 24 hours. Rather, this would be a requirement that the dentist be contacted within 24 hours of the emergency to provide plans and orders for the resident. Those plans and orders may then include a dental visit or may include instructions for nursing home staff to implement as part of the oral health care plan. By setting these requirements in rule, we intend to clarify what some of the standards of practice for emergency dental services provided in nursing homes are.

Subpart 4 Dental Records: This subpart is being proposed to define what is expected of nursing homes in terms of keeping records of dental visits. The information required is routinely available from the dental care provider. It is necessary to specify the information to be maintained in the resident record to provide a standard for dental providers and nursing homes to follow for maintaining records on each resident. It is reasonable to require the listed items for the dental record because the services provided, medications administered, consultations, and follow-up orders will impact on the resident and other cares and services the resident receives.

4658.0730 NURSING HOME REQUIREMENTS.

Subpart 1 Training: Because daily oral care is so important to the ongoing health and well-being of the nursing home resident, it is necessary to specify that nursing home staff providing that care be trained and competent to provide oral care. It is reasonable to expect that there should be initial and ongoing training of nursing home staff to ensure the highest level of oral health and functioning possible for the residents.

Subpart 2 Written agreement: The proposed language here corresponds with the current federal and state regulatory language and includes some new language. Nursing homes have been required to provide dental services for their residents and to have a written agreement for emergency dental care. It is reasonable to require dental consultation on nursing home policies, either directly or indirectly, as well as oral health training for the staff who will be providing or assisting the residents with the daily oral cares to assure that care is given in accordance with professional standards of quality. It is necessary to specify what the nursing home must include in their written dental provider agreement in order to ensure that these standards of care are available and provided to the residents. As one dentist states, "The dental profession has an obligation to improve the oral health of nursing home patients as well and should provide leadership and innovation. Dental professionals can be advocates for patients....we can provide

in-service training and hands on instruction to staff, residents, and family caregivers."[12]

Subpart 3 Making appointments and Subpart 4 On-site services: The proposed language incorporates the intent of the current state licensing language while corresponding to current federal certification language. It is reasonable to have this proposed rule because without it one can expect identifiable negative outcomes to the resident if the resident is not obtaining appropriate dental services, both in terms of their oral health and in terms of their general physical status. These negative outcomes include but would not be limited to gum or mouth disease, inability to chew, poor oral hygiene, toothaches, and broken dentures.

The proposed language is reasonable because it clarifies what the nursing home must do to accommodate meeting the residents' oral health needs and it clarifies that the nursing home may either get the resident to the dentist or bring the dental services into the nursing home. This ensures the resident's rights to receiving the appropriate oral care to meet the residents' needs, regardless of any transportation problems.

Subpart 5 List of dentists: The current state rule requires the nursing home to maintain the name and address of the emergency dentist at each nurses' station. This proposed language expands on that requirement by stating that the nursing home must maintain a list of dentists available to the residents of that nursing home. It is reasonable to have this list because it offers residents a choice of dentists in the area. This list of dentists must be readily available to nursing staff. It is necessary to have a rule maintaining and having an accessible list of dentists to assure that staff are able to obtain care for residents when needed. There can be problems of access to dental services in some areas of Minnesota, particularly for persons whose dental care is paid for by Medicaid (medical assistance, or MA). Also, there have been problems of access to the dentist's office, especially for residents in wheelchairs. These include access to the building that the office is located in, access to the office itself, and access to the dentist's chair. The federal Americans With Disabilities Act requirements have been and will continue to be advantageous towards eliminating or dealing with those barriers.

4658.0750 PENALTIES FOR PHYSICIAN AND DENTAL SERVICES.

See the discussion in part 4658.0045, above.

Some parts of this section of proposed rules are not significantly different from current rule language. The proposed fines for noncompliance with those sections are the same as those for the comparable sections in the current rules. This includes the fines for proposed parts 4658.0705; 4658.0710, subparts 1, 2, and subpart 3, item A; 4658.0715; 4658.0720, subpart 2; 4658.0725, subparts 1 and 4; and 4658.0730, subpart 5.

The fines for noncompliance with correction orders for parts 4658.0700; 4658.0710, subpart 3,

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[12] Ofstehage, J.: "OBRA '87 Regulations for Nursing Homes: Implications for the Dental Profession." Northwest Dentistry, November - December 1992: p. 15.

items B & C, and subpart 4; 4658.0720, subpart 1; 4658.0725, subparts 2 and 3; and 4658.0730, subparts 1 through 4 have been established in accordance with the eight tier level of fines developed to correlate with the impact of noncompliance on the resident.

Part 4658.0700, subpart 1, states that the medical director must be a licensed physician in Minnesota. The fine proposed for noncompliance with this part is set at $100 which is the proposed fine for rules that relate, in a general nature, to the administration and management of the nursing home. This amount is reasonable because it is necessary that the medical director be qualified to perform his duties.

Part 4658.0700, subpart 2, items A through F, address the duties of the medical director. The proposed fine for noncompliance with this part is set at $300, the penalty assessment assigned to those rules which are necessary to assure that the service is properly provided. This amount is reasonable because noncompliance with these rule parts would affect the quality of care that is provided to the residents. Compliance with these rule parts is necessary to ensure the provision of services to be done in a safe and effective manner.

Part 4658.0700, subpart 2, item G addresses the medical director's participation on the Quality Assurance (QAA) Committee. The proposed fine set for noncompliance with this part is set at $100 and relates to the administration and management of the nursing home. It is reasonable to set this amount because the medical director's involvement on this committee would help ensure the health and safety of residents.

The penalty assessment for noncompliance with correction orders addressing part 4658.0710, subpart 2, items B and C is set at $300, the penalty assessment assigned to rules which are necessary to assure that services are properly provided. This amount is reasonable because these rule parts would affect the quality of care provided to residents. The requirements for admission orders, and current history and physicals would relate to meeting resident needs. Noncompliance with these rule parts would result in the inability to adequately meet the needs of the residents and the Department believes that the $300 fine is appropriate.

Part 4658.0710, subpart 4, addresses the responsibility of physicians during physician visits. The fine for noncompliance with this part is set at $100, the penalty assessment for rules related to the administration and management of the nursing home. It is reasonable to set this amount because noncompliance with this rule has the potential for jeopardizing the health safety, treatment, comfort or well-being or residents. Compliance with this rule is necessary to ensure continued health and safety related to resident care.

The fine for noncompliance with correction orders for part 4658.0720, subpart 1, is set at $300. This is the penalty assessment assigned to those rules that are necessary to ensure that the service is properly provided. It is reasonable to set this amount because noncompliance with this rule would result in the inability to meet the needs of the residents. Compliance with this rule is necessary to ensure that the provision of oral care is done in safe and effective manner.

Parts 4658.0725, subparts 2 and 3 address routine and emergency oral services. The penalty assessment for noncompliance with this part is also set at $300, for reasons as stated above.

This amount is reasonable because noncompliance with these rule parts would affect the quality of routine and emergency oral care that is provided to residents. Compliance with these rule parts is necessary to assure the safe and effective provision of oral care to residents when needed.

The penalty assessment for noncompliance with correction orders addressing part 4658.0730, subparts 1 through 4, is set at $300 which is assigned to those rules which are necessary to ensure that services are properly provided by the nursing home. This amount is reasonable because noncompliance with these rule parts would affect the quality of dental services that are provided to residents. Compliance with these rule parts is necessary to ensure that the provision of dental services is done in a safe and effective manner.

INFECTION CONTROL

PART 4658.0800 INFECTION CONTROL.

This part is proposed for the state licensing rules for nursing homes to delineate the expectations for an effective infection control program. Because this would be a new area in the state licensing rules for nursing homes, the proposed language is fairly descriptive of the types of activities and components which must be included in the infection control program, while allowing latitude for nursing homes to determine how best to design and implement an effective and appropriate infection control program designed specifically for their facility's resident population, operations, and physical plant layout. With the current emphasis on appropriate infection control practices in the health care industry, it is necessary for the state nursing home licensing rules to include a part on an infection control program. The proposed language is reasonable because it clearly and concisely states the minimum requirements for an effective infection control program. Since all nursing homes already practice infection control, there should be little or no fiscal or operational impact on those that have an effective infection control program. And, nursing homes may choose (or may need) to include more elements in their infection control program; those listed in this rule are the minimum elements which must be included in each nursing home's infection control program.

Some of the language being proposed is derived from information published by the Association for Practitioners in Infection Control (APIC).[13] Other language, specifically that relating to tuberculosis control, is derived from information provided by the MDH Division of Disease Prevention and Control. Publications addressing infection control issues from the national Centers for Disease Control (CDC) and from other professional organizations and groups were reviewed during the course of language development; concepts from those publications were incorporated where suitable.

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[13] Smith, P., Rusnak, P, "APIC Guidelines for Infection Prevention and Control in the Long-Term Care Facility," American Journal of Infection Control, Volume 19 No. 4, August 1991.

Subpart 1 Infection control program: Under these proposed rules, an infection control program would be established and maintained by the nursing home. The proposed requirement for an infection control program is necessary and reasonable to ensure a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection. Both the risk factors for infection specific to the resident population and the nature of the facility must dictate the scope and focus of the infection control program.[14] Besides being a health protection for residents and staff, an effective infection control program can save nursing homes money by averting the use of supplies and staff time necessary to combat infections. This infection control program would address the prevention, tracking, and control of outbreaks of infectious diseases, for both residents and staff, specific to that nursing home. The program would accomplish these tasks through a variety of systems, policies, and procedures addressing resident and employee health and infection control practices. These elements are described in subpart 3 of this part.

Subpart 2 Direction of program: It is necessary and reasonable to require the nursing home to assign one person to be responsible for directing the infection control program to assure consistency and effective program implementation. With these proposed revisions, the person directing the infection control program must be either a licensed nurse or a licensed physician because of the basic medical or nursing knowledge necessary to this role. This requirement would not entail the facility to hire a staff person specifically to direct the infection control program, although some of the larger nursing homes may in fact do that (or, more likely, have already done that). Generally, nursing homes already have a designated infection control practitioner (ICP), who commonly has other duties and responsibilities in addition to the infection control program. We do not want to limit the assignation of responsibility for the infection control program to a specific staff position. Rather, the nursing home should determine who among their staff is most appropriate, through education, experience, and interest, as well as availability, to direct the infection control program as developed specifically for that nursing home.

Because of the scope of the program and the importance of having an effective infection control program, the person directing the nursing home's program must have education and experience in infection control sufficient to carry out the program at that nursing home. That education and experience needed may vary widely between nursing homes because of the different sizes, populations, and specializations of the various nursing homes. However, because of the importance of having an effective infection control program, and the knowledge of issues in long term care infection control necessary to direct such a program, the person responsible for directing that program must be a licensed registered nurse or a licensed physician. It would be the responsibility of the nursing home to determine what additional qualifications would be necessary for the person responsible for the infection control program at that facility, and then to assign a person to that role who has those qualifications. It is reasonable to expect the nursing home to assume this responsibility because the administrator and / or the governing board should be expected to be familiar with the operational needs of the home and so would be able to determine the necessary qualifications.

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[14] Pritchard, V., "Infection Control Programs for Long-Term Care," Journal of Gerontological Nursing, July 1993:29-32.

It is necessary and reasonable to require that a sufficient number of staff be assigned to assist with the infection control program by the nursing home to insure that the infection control program is developed, maintained, and functions effectively for the residents and staff. Again, this leaves the responsibility and the opportunity to the nursing home to determine what staffing numbers and qualifications are necessary to meet the needs of their residents and to fulfill the requirements of their infection control program. The needs of the nursing homes may vary greatly depending on the residents being served, the physical plant of the nursing home, staff qualifications, or other factors. The nursing home is best qualified to make those determinations. The Department of Health will judge whether or not there are sufficient staff assigned to the infection control program by assessing whether the infection control program appropriately addresses the needs of the nursing home, and if the program as developed by the nursing home is being implemented.

Subpart 3 Policies and procedures: This subpart addresses the components which are essential to the development and operation of an effective infection control program. The proposed language requires the nursing home to develop infection control policies and procedures. These will vary depending on the needs and situations of the residents and staff of that facility, and also on the physical plant. It is necessary and reasonable to require these policies and procedures in order to control infections and to prevent infections from occurring. This is good nursing practice, and what is expected from consumers when they become residents of a nursing home. Some nursing homes could be expected to have quite extensive policies and procedures because of the nature of their business or specialization in services provided. Most likely these nursing homes already have those policies and procedures in place because they have needed to address their concerns. Other nursing homes might need only very minimal guidelines in place because the population they generally serve does not ordinarily come into the facility with infections, nor develops a disproportionate number of infections once admitted.

The proposed rules provide certain parameters within which the nursing home has considerable latitude to determine the types of systems, policies, and procedures which are appropriate for their facility. This design of the proposed rules places the responsibility on the nursing home to be aware of the infection control needs and circumstances of its residents, staff, and physical plant layout, and to systematically and effectively address those infection control needs and circumstances. These infection control policies and procedures might deal with any number of issues, such as admission, discharge, or transfer of residents with infectious diseases, handwashing and handwashing facilities, disinfection and sterilization, housekeeping, laundry, infectious waste, ventilation, and any other applicable issue.

Item A requires the nursing home to conduct surveillance designed to collect data to establish nosocomial infection rates and to identify the major sites of infection, their cause or origin, and associated complications. Nosocomial infections are those which the resident gets while in a health care facility, such as a hospital or nursing home. Surveillance of nosocomial infections based on systemic data collection allows for the monitoring of infection types and rates of occurrences. It is necessary and reasonable to require this surveillance since that is one of the factors in infection prevention and control. It is necessary to have knowledge of what the rates of infections are in order to determine how best to prevent or control the most common infections, as well as the less common ones. "It has become clear that much more data on rates,

risk factors, and management of infections in residents of such facilities are needed if the quality of resident care and the cost-effectiveness of infection control programs are to be optimized."[15] By monitoring these nosocomial infections, it is expected that the nursing home could deal more effectively with any nosocomial infections which may develop, and could possibly decrease the number of nosocomial infections through appropriate prevention efforts.

Item B requires the nursing home to include in its infection control program a system for detection, investigation, and control of outbreaks of infectious diseases. These activities may begin through the use of the data collected under item A of this subpart. Detection, investigation and control can take many forms, depending on the nature of the outbreak or epidemic, and depending on each individual nursing home's population and physical plant. It is necessary and reasonable to require a system for the detection, investigation, and control of outbreaks of infectious diseases because it is essential to manage those outbreaks to restore the affected resident or residents to health and to prevent other residents or staff from catching the infectious disease. By having a system established prior to outbreaks, the nursing home will be able to detect the outbreaks more rapidly once they occur; there will be a plan to follow already set up, thereby reducing the amount of time spent investigating and preparing to address the outbreak. With a system in place, the nursing home will be able to move quickly to control any outbreaks of infectious diseases, thus protecting the health and safety of residents and staff. This protection applies to both the infected residents or staff and the noninfected ones.

Item C requires the nursing home to develop and implement systems for isolation and precautions to reduce the risk of transmission of infectious agents. Again, there is a variety of methods the home may choose to design or implement, depending on the infection. There are guidelines published by the national Centers for Disease Control (CDC) and there are Occupational Safety and Health Act (OSHA) regulations dealing with isolation issues and Universal Precautions to assist nursing homes in designing the isolation and precautions systems appropriate to their facility. There are also guidelines published by various professional organizations, and many other books and publications address isolation and precautions systems. It is necessary and reasonable to require nursing homes to have systems for isolation and other precautions to prevent the spread of infection from resident to resident, from the resident to staff, or from staff to the resident. Isolation procedures many also lessen the risk of infection in residents with compromised immune systems. These precautions promote the health and safety of the residents and staff.

Item D requires the nursing home to provide inservice education in infection prevention and control for the staff of that nursing home. It is necessary and reasonable to require this staff training to help prevent and control infections, which is part of the provision of appropriate nursing care, providing protections to the residents and staff. Current federal regulations require annual inservice training for nursing assistants based on the outcome of their annual performance review; that inservice training is to address areas of weakness as identified in the performance reviews of the nursing assistants, and may address the special needs of residents as determined

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[15] McGeer, A., et al., "Definitions of Infection for Surveillance in Long-term Care Facilities," American Journal of Infection Control, Vol. 19, No. 1, Feb. 1991:1.

by the facility staff. For example, education in early symptom recognition is beneficial to individuals with direct resident care responsibility, and to the residents they provide care for. It is likely that it would also be beneficial for the nursing home to provide infection control training to other staff with resident contact, such as housekeeping, activities, food services, therapies, or other resident services. During the course of review and revision of these rules, it was reported to the Department of Health that residents frequently confide in these non-nursing staff about their condition. In addition, these non-nursing staff may observe potentially infectious circumstances or actual infections while performing their duties. It follows, then, that all nursing home staff should have sufficient infection control training to know when and to whom to report any information about infectious diseases or potential infectious diseases. The nursing home would be expected to determine what types of infection prevention and control education is appropriate to the needs of their residents and the facility, based on the acuity levels of the residents, other resident needs, and the physical plant of the nursing home. It is reasonable to expect that part of this inservice education would include making all staff aware of the infection control policies and procedures which exist for that nursing home.

Item E requires the nursing home to have a resident health program to assist in the prevention and treatment of infections. This resident health program is to include, at a minimum, an immunization program, a tuberculosis monitoring program (as defined in the proposed part 4658.0810, which is an update of current language in part 4655.4700), and policies and procedures dealing with resident care practices. The immunization program would address the needs of the residents, taking into account their susceptibility to infectious diseases and the appropriateness of immunization for the resident. This would not be a requirement to immunize all residents against all possible infectious diseases, but rather a requirement that the nursing home have a program for relevant resident immunizations. For example, the nursing home might address, for each resident, the benefits and disadvantages of the annual recommended influenza vaccination. The tuberculosis monitoring program must meet the rule standards. The policies and procedures dealing with resident care practices will likely vary among nursing homes; the expectation is that the nursing home will have policies and procedures to address their specific resident circumstances, such as general resident population, their physical conditions and acuity levels, size of the population, and the layout of the physical plant.

Item F requires the nursing home to develop and implement employee health policies and infection control practices. These may include, for example, initial assessment of employee health, sick leave policies, return-to-work policies, continuing and inservice education, handwashing procedures, and post-exposure policies for certain infections. Employees can be a contributing factor to the introduction and spread of infections in long term care facilities. Whether and when employees who have missed work days because of illness may be allowed to return to work can reasonably be expected to be addressed in the nursing home's policies and procedures dealing with the employee health program. The employee health policies will likely address a tuberculosis monitoring program, which must meet the proposed rule standards in 4658.0815 (a revision of the current rule part 4655.3000). It is necessary and reasonable to include this requirement for employee health policies and infection control practices in the rule because, by developing and implementing policies and procedures and educating employees on them, nursing homes can help prevent the spread of infections to residents and to other staff.

Item G requires the nursing home to have a system for reviewing antibiotic utilization. This requirement is necessary and reasonable to include since antibiotic - resistant bacteria can pose a significant health hazard in nursing homes. This resistance develops largely as a result of antibiotic usage, especially long-term usage. "Antibiotic-resistant bacteria pose a significant hazard in the LTCF, and this resistance develops largely as a consequence of antibiotic usage."[16]

Recent articles seem to indicate that there is an increase in antibiotic-resistant strains of some infectious diseases, and this could become a significant health hazard if treatment options become severely limited.[17],[18],[19],[20],[21] The nursing home would determine how widespread the use of antibiotics is in that facility, and would then develop and implement their review system based on that determination. The amount of antibiotic usage in that nursing home will depend on the residents and their health status or problems. This system of antibiotic utilization review may be designed and implemented by the nursing home's infection control designee, the administrator, the medical director, consulting pharmacist, or other qualified person.

Item H requires the nursing home to have a system for review and evaluation of products which affect the infection control program. This does not mean the infection control program or practitioner must review all products used by the nursing home. This does mean that there is a system within the nursing home to review and evaluate products which could affect infection control within the facility. These may include, for example, disinfectants, antiseptics, gloves, disposable diapers, and so on. The applicability, effectiveness, and costs of the items would

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[16] Smith, P., Rusnak, P, "APIC Guidelines for Infection Prevention and Control in the Long-Term Care Facility," American Journal of Infection Control, Volume 19 No. 4, August 1991.

[17] Kotthoff-Burrell, E., "Health Promotion and Disease Prevention for the Older Adult: an Overview of the Current Recommendations and a Practical Application," Nurse Practitioner Forum, Dec. 1992.

[18] Bennett, M.E. *et al*, "Recommendations from a Minnesota Task Force for the management of persons with methicillin-resistant *Staphylococcus aureus*," American Journal of Infection Control, Vol. 20, No. 1, Feb. 1992: 42.

[19] Boyce, John M., *et al*, "Methicillin-Resistant Staphylococcus aureus [MRSA]: A Briefing for Acute Care Hospitals and Nursing Facilities," Infection Control and Hospital Epidemiology, Special Report, Vol. 15, No. 2, Feb. 1994: 105.

[20]18 National MDR-TB Task Force, "National Action Plan to Combat Multidrug Resistant Tuberculosis," Centers for Disease Control, U.S. Department of Health and Human Services, April 1992.

[21] O'Boyle Williams, C. and Feldt, K., "A Nursing Challenge: Methicillin-Resistant Staphylococcus Aureas in Long-Term Care," Journal of Gerontological Nursing, July 1993:22-28.

likely be considered in product selection. It is necessary to include this product review and evaluation requirement in the licensing rules to ensure awareness of available products, which can be expected to result in the justified use of appropriate products for the situation. This system for review and evaluation of products is a standard of practice among infection control practitioners.

Item I requires the nursing home to have methods for maintaining awareness of current standards of practice in infection control. Infection control practices are evolving as knowledge increases in this area. Consequently, it is appropriate for the rules to require the infection control program to be aware of current standards of practice. It is necessary for, and reasonable to expect, the nursing home to remain up to date on what sorts of infections are prevalent, and what types of controls to prevent those infections and methods to treat those infections are being found to be most efficacious. There are a number of sources which provide this information, including federal publications from OSHA and CDC, as well as the Minnesota Department of Health. Provider organizations commonly inform their members of significant changes in current standards or findings. There are also associations of persons who work in infection control, such as APIC, which share a wealth of information among members, both formally and informally. And there are many periodicals which frequently include articles on infection prevention and control; these can be accessed at local libraries or by subscription. It is reasonable to expect the nursing home to remain up-to-date on what the current standards of practice are, and to implement any changes to their infection control program as are appropriate to the needs of that nursing home, in order to provide a safe environment for the residents, staff, and visitors.

PART 4658.0805 PERSONS PROVIDING SERVICES.

This proposed part is a revision to the current parts 4655.2600 and 4655.2900. It is necessary and reasonable to revise the language to conform more closely to current situations and practices in employee health standards, taking into account other applicable regulations. The proposed language corresponds with the state rules applicable to supervised living facilities. In addition, the proposed language meets the standards of the federal Americans With Disabilities Act, which includes the requirement that a "disabled" person (which includes a person with a communicable disease) not be disqualified from employment unless the person poses a direct threat to the health of others. Under the newly proposed section 4658.0800, Subpart 3, item G, the nursing home's infection control program would include employee health policies, which can reasonably be expected to address the intent of language in the current part 4655.2600 ("...mentally and physically capable of performing the work..."). The proposed language here in this part clarifies the circumstances when persons with communicable diseases, whether employees or volunteers, should not be allowed to provide cares to residents ("until such time that a physician certifies..."). This proposed rule part references existing state rules found at Part 4605.7040, which is a listing of communicable diseases required to be reported to the Minnesota Department of Health by nursing homes as well as other parties.

It is necessary to revise this part of the rules to clarify its intent; that is, to assure a safe environment for residents, staff, volunteers, and visitors to the nursing home. The language being proposed is reasonable because it provides specific information on desirable outcomes,

namely what is to be expected from the nursing home to assure safety to residents, staff members, volunteers, and visitors.

PART 4658.0810 RESIDENT TUBERCULOSIS PROGRAM.

Subpart 1 Tuberculosis test at admission: Subpart 1 of this part is a relocation of language currently found in part 4655.4700, among the items which must be included in the medical record upon admission. As part of the revision of these nursing home licensing rules, we are attempting to group related rules. It is more appropriate that these rules on a resident tuberculosis program be placed among the other rules relating to infection control. It is necessary to include a rule requiring a tuberculosis test at admission to provide protection to the health and safety of other residents and staff, and to establish a baseline for the newly admitted resident's status. "Until the mid-1980's, the number of tuberculosis (TB) cases in the United States had been decreasing. At that point, the decline in the number of TB cases in the United States ended; some areas even began to see increases."[22] The language is reasonable because, while basically being the same requirement as current rule, it allows a longer time period prior to admission for the Mantoux test or chest x-ray, while keeping the health and safety precautions for residents and staff. Medical contraindications such as a previous adverse reaction to a tuberculin skin test should be included as an exemption to Mantoux testing. The phrase "within the past three months" is added to clarify that the Mantoux, as well as the chest x-ray, may be as much as three months in advance of admission. This is a more reasonable time frame, consistent with other tuberculosis screening programs.

Subpart 2 Evaluation of symptoms: Subpart 2 is added to expand and clarify surveillance activities to include evaluation of persons with symptoms compatible with tuberculosis. It is necessary to add this subpart to the nursing home licensing rules to protect the health and safety of residents and staff. According to a report published by the Centers for Disease Control (CDC):

> "Persons ≥65 years of age constitute a large repository of *Mycobacterium tuberculosis* infection in the United States. Tuberculosis case rates are higher for this age group than for any other. In 1987, the 6,150 tuberculosis cases reported for persons ≥65 years of age accounted for 27% of the total U.S. tuberculosis morbidity, even though this age group represents only 12% of the U.S. population.....Elderly nursing home residents are at greater risk for tuberculosis than elderly persons living in the community."[23]

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[22] Lancaster, E., "Tuberculosis Comeback: Impact on Long-Term Care Facilities," Journal of Gerontological Nursing, July 1993:16.

[23] Centers For Disease Control, "Prevention and Control of Tuberculosis in Facilities Providing Long-Term Care to the Elderly - Recommendations of the Advisory Committee for Elimination of Tuberculosis," Morbidity and Mortality Weekly Report Recommendations and Reports, Vol. 39, No. RR-10, July 13, 1990:7-20.

Incidence rates of tuberculosis in the United States are rising, and multi-drug resistant cases of TB are being identified. There is a 50% fatality rate for untreated TB, so it is essential to identify potential cases as soon as possible.

> "Recent data from New York City indicate that 33% of current cases are resistant to one or more drugs, and 19% are resistant to both isoniazid and rifampin. When resistance to both isoniazid and rifampin is present, the course of treatment increases from 6 months to 18-24 months, and the cure rate decreases from over 95% to approximately 60% with optimal care."[24]

The language proposed is reasonable because it is consistent with current standards of practice and can be implemented by current facility personnel or the resident's attending physician. It corresponds with and supplements language found in other portions of the infection control - related proposed rules.

PART 4658.0815 EMPLOYEE TUBERCULOSIS PROGRAM.

Subpart 1 Responsibility of nursing home: This proposed subpart is a revision of the current part 4655.3000 subpart 1. The language "show freedom from tuberculosis" was changed to "screened for tuberculosis" because the purpose of this rule is not only to identify tuberculosis disease and thereby prevent introducing it into the nursing home, but also to obtain a baseline Mantoux test result upon admission. This subpart is necessary and reasonable because it incorporates current standards of practice in infection control, designed to protect the health and safety of residents and staff.

Subpart 2 Tuberculin test: This proposed subpart is a revision of the current part 4655.3000 subpart 2. Again, this subpart is necessary and reasonable because it provides protection for residents' and employees' health. It is appropriate to include medical contraindications as an exemption to Mantoux testing, such as a previous adverse reaction to a tuberculin skin test. A Mantoux test within the past three months, rather than the previously required 45 days, is acceptable. This is a more reasonable time frame, consistent with other tuberculosis screening programs. The statement, "If the tuberculin test is negative, the employee shall be considered free from tuberculosis" is omitted in these proposed rules because a negative Mantoux test does not definitively rule out tuberculosis: An employee exhibiting symptoms, regardless of Mantoux test results, would require further evaluation (see proposed subpart 5).

Subpart 3 Positive test: This proposed subpart is a revision to the current part 4655.3000 subpart 3. It is necessary and reasonable to include a rule addressing those nursing home employees who have had a positive reaction to the tuberculin test in order to assure their not spreading tuberculosis to residents and other staff. The current standards of practice, from infection control practitioners and the MDH Division of Disease Prevention and Control, state that persons with new positive Mantoux test reactions, who do not take preventive therapy,

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[24] Commissioner's Task Force on Tuberculosis, "Recommendations of the Commissioner's Task Force on Tuberculosis," Minnesota Department of Health Disease Control Newsletter, Vol. 22, No. 2, March 1994:9-16.

should be monitored for two years by annual chest x-ray. This would include pre-employment chest x-rays if new employment begins during that two year time period, and annual chest x-rays until two years have passed. Thereafter, the likelihood of detecting tuberculosis disease is too low to justify any repeat chest x-ray requirement. A chest x-ray with the past three months, rather than 45 days, is acceptable. This is a reasonable time frame, consistent with other tuberculosis screening programs. Again, the language "considered free from tuberculosis" has been omitted, in this instance because individuals with positive Mantoux test reactions have tuberculosis infection and are not free from tuberculosis.

Subpart 4 Written documentation of compliance: The current part 4655.3000, subpart 4, would be revised to the language contained in the proposed subpart 4. It is necessary to retain the intent of the current rule, ensuring that there is documentation of compliance with the previous subparts, so there is an available record of compliance. The revision no longer requires nursing homes to keep the documentation in the personnel file, as long as it is maintained by the nursing home. The proposed revision is reasonable because it maintains that requirement for proof of compliance, while being consistent with the federal Americans With Disabilities Act of 1990 [42 U.S.C. §12113(d)(3)(B), which requires employers to keep employee medical information separate from other personnel records.

Subpart 5 Evaluation of symptoms: As above in the proposed subpart on evaluation of symptoms of tuberculosis in residents, it is necessary to include a subpart on evaluation of symptoms of tuberculosis in employees. Subpart 5 is added to expand and clarify surveillance activities to include evaluation of persons with symptoms compatible with tuberculosis. It is necessary to add this subpart to the nursing home licensing rules to protect the health and safety of residents and staff. Although the rate is lower in Minnesota than elsewhere in this country, incidence rates of tuberculosis are rising, and multi-drug resistant cases of TB are being identified. There is a 50% fatality rate for untreated TB, so it is essential to identify potential cases as soon as possible. The language proposed is reasonable because it is consistent with current standards of practice and can be implemented by current facility personnel or the resident's attending physician. It corresponds with and supplements language found in other portions of the infection control - related proposed rules.

PART 4658.0820 FOOD POISONING AND DISEASE REPORTING.

This proposed part is a revision of the current part 4655.4300. The language would be updated to provide specific information to nursing homes on the reporting of any occurrence of food poisoning or reportable disease. It is necessary and reasonable to amend the language to include the applicable address in order to provide public information to nursing homes on the appropriate place to report diseases. This will lead to increased efficiency in the reporting process, both for nursing homes doing the reporting and the Department of Health's collection of reports. This increased efficiency will prevent the spread of communicable diseases within the nursing home and to the community at large.

PART 4658.0850 PENALTIES FOR INFECTION CONTROL.

See the discussion on the establishment of fining levels in part 4658.0045, above.

The fines for noncompliance with correction orders for parts 4658.0800 through 4658.0820 have been established in accordance with the 8 tier level of fines developed to correlate with the impact of noncompliance on the resident. Those proposed rule parts which directly correspond with existing rules generally are assigned the corresponding existing penalty assessment. There are a few proposed parts which are new or are sufficiently different from existing rules to warrant an explanation of their assigned penalty assessment. These include the proposed part 4658.0800, 4658.0805, and 4658.0815, subpart 5.

The penalty assessment for the proposed part 4658.0800 is set at $300. The $300 level of fines is assigned to those rules which are necessary to ensure that services are properly provided by the nursing home. The proposed rules addressing an infection control program are directly related to the actual provision of those services and compliance with these rules is necessary to assure that the actual provision of the services is done in a safe and effective manner. Noncompliance with these rules would result in the inability to adequately meet the needs of the residents and the Department believes that the $300 fine is appropriate.

The penalty assessment for the proposed part 4658.0805 is set at $300. Again, the $300 level of fines is assigned to those rules which are necessary to ensure that services are properly provided by the nursing home. The proposed rule addressing the prohibition of persons with a communicable disease or infected skin lesions from providing services is directly related to the actual provision of services and compliance with this rule is necessary to assure that the actual provision of the services is done in a safe and effective manner. That is, persons providing services must not be permitted to work in the nursing home until there is a physician certification that the person's condition will not endanger others' health. Noncompliance with this rule would result in the inability to ensure that services are properly provided to residents, and could thus endanger the health, safety, and well-being of residents, and the Department believes that the $300 fine is appropriate.

The penalty assessment for the proposed part 4658.0815, subpart 5 is set at $300. As with the proposed part 4658.0810, this proposed part addressing the requirement that employees exhibiting symptoms consistent with tuberculosis be evaluated within 72 hours by Mantoux test or chest x-ray is directly related to the actual provision of services in the nursing home, and compliance with this proposed rule is necessary to assure that the actual provision of the services is done in a safe and effective manner. That is, employees who may have tuberculosis must be evaluated with 72 hours to ensure that they will not be spreading tuberculosis to residents or other staff, nor further endangering their own health, if they are found to have tuberculosis. Noncompliance with this rule would result in the inability to ensure that services are properly provided to residents, and could thus endanger the health, safety, and well-being of residents, and the Department believes that the $300 fine is appropriate.

MEDICATION AND PHARMACY SERVICES

4658.1300 MEDICATIONS AND PHARMACY SERVICES; DEFINITIONS.

The language proposed in part 4658.1300 is a revision to the current rule language found in part 4655.7720. Most of the current language has been deleted or not carried over to this proposed chapter because that language is outdated. The definitions of "Schedule II drugs", "pharmacy services", and "drug regimen" are needed to clarify subject matter in these proposed rules.

4658.1305 PHARMACIST SERVICE CONSULTATION.

The language in the proposed part 4658.1305, items A and B, matches the federal regulatory language. The proposed language in item A is necessary because it requires the nursing home to obtain the services of a licensed pharmacist to provide consultation on all aspects of pharmacy services. Qualifications of pharmacists make it appropriate for them to provide this service. Not only is this a good standard of practice, but it is in the best interests of the residents.

It is necessary to require the proposed language in item B because it allows the nursing home to develop its own system for reconciling the receipt and disposition of controlled drugs. A system is needed for this reconciliation to ensure that a nursing home is able to locate and remedy any shortages of controlled drugs that may occur. The language being proposed in items A and B is reasonable because it matches federal certification language which 99% of the nursing homes in Minnesota already comply with.

The language in proposed item C is patterned after federal certification language. The proposed language is necessary to ensure the accuracy of controlled drug records. This proposed rule is reasonable because it does not prohibit shortages of controlled drugs, but only requires that a system is established to periodically reconcile controlled drugs.

4658.1310 DRUG REGIMEN REVIEW.

The proposed 4658.1310 would be new language in these state licensing rules. Items A and B are patterned after federal certification language. Item A contains a grammatical change from monthly review to 30 day review. This specificity is needed to clarify the expected frequency of the pharmacist review and for ease in enforcement. It does not prohibit a review to be done more frequently if the resident's condition and the drugs the resident is taking indicates a concern that needs more immediate attention. The reference to Appendix N of the State Operations Manual is included to ensure consistency in the reviews. This document is located at the Minnesota Law Library, and is available through the Minitex system.

The proposed item B states that the pharmacist report must be acted upon and defines "acted upon" to ensure that the director of nurses and attending physician are aware of what this means. It expands on current federal certification language by giving a time frame for this to be completed. It is reasonable to include this language in the proposed rule to ensure that responses to irregularities are addressed in a timely manner. The director of nursing or attending physician are not required to agree with the pharmacist's report nor are they required to give

rationale for their decisions. They must, however, act on the report which can be done by either accepting or rejecting the report and signing their names or by some other action.

The proposed item C was included in these proposed rules as a specific request from pharmacists. The proposed language includes additional steps to have pharmacist recommendations reviewed when attending physicians do not concur with the pharmacists' recommendations. This proposed language is reasonable to ensure that potential resident outcomes have been appropriately assessed. Proposed language in items A, B, and C are necessary and reasonable to ensure that medications are taken safely, without apparent irregularities, and to notify an individual in authority to correct any potential problem affecting the health, safety, and welfare or residents.

4658.1315 UNNECESSARY DRUG USAGE.

New language to these pharmacy rules is being proposed under part 4658.1315 relating to unnecessary drug usage. The proposed language in subpart 1 is patterned after federal certification language. It is necessary to include this proposed language to assure that residents receive care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the resident's comprehensive assessment and plan of care. The language is reasonable because it corresponds with proposed part 4658.1310.

Nursing home staff are constantly monitoring the physical, mental, and psychosocial well-being of residents. It is necessary to include a mechanism for monitoring unnecessary drug usage in the proposed rules to assure that residents are not receiving drugs which may alter their physical, mental, and psychosocial well-being or are otherwise inappropriate for any reason. Medications are a primarily therapeutic modality and with nursing home cares becoming more skilled there needs to be protection for residents. It is reasonable to include monitoring for unnecessary drugs to assure that any problems are addressed. Reporting irregularities in the drug regimen to the resident's attending physician is an additional safety step to assure continuous resident health, safety, and well-being. Additional proposed language includes steps to have pharmacist recommendations reviewed when attending physicians do not concur with the nursing home's recommendations. The proposed language in subpart 2 also ties in with 4658.1310, because the 30 day drug review should also determine if residents are receiving unnecessary drugs.

4658.1320 MEDICATION ERRORS.

The proposed part 4658.1320, items A and B would be new language in these state licensing rules. The five percent acceptable standard comes from federal certification language. Other language is patterned after federal certification guidelines and also includes additional language. It is necessary to require nursing homes to have less than five percent medication error rates because a medication error rate of five percent or greater could indicate that a nursing home has systematic problems with its drug distribution system. This could create serious problems for residents. It is reasonable to define "medication error" and "significant medication error" in this proposed language to clarify the intent of the proposed rule.

The proposed item C is a revision to the current part 4655.7700, subpart 8 and 4655.3900, subpart 3. Proposed language deletes the requirement that medications be administered as ordered by the physician. The language is updated to reflect that persons other than physicians order medications. Current language also requires in part that any medication error or patient reaction be reported to the physician "at once." It is reasonable to delete the reference to "at once" and change the proposed requirement to notifying the physician of any "significant" medication errors because significant errors could affect the health and well-being of the resident. It is necessary to have this proposed change because many errors can be minor in nature and would not adversely affect a resident, thus not necessitating a call to the physician. Significant medication errors should be reported as soon as possible.

Current language at 4655.7700, subpart 8 also requires notification of medication error (or resident reaction to the error) to the physician only. In addition to notifying the physician, the proposed language requires notification of the resident or the resident's legal designee of "significant" medication errors. It is reasonable to include this language because it is the resident's or legal guardian's right to be told of the resident's condition, or impending condition because of a significant medication error and is consistent with federal certification language.

Current rule language in part 4655.7700, subpart 8, requiring an explanation of medication errors or resident reactions in the resident's chart, would remain the same except proposed language would require this information to be put into the "resident's clinical record" which corresponds with language in other parts of the proposed rules.

Current part 4655.3900, subpart 3 requires nursing homes to complete an incident report whenever there is an error in drug administration. It is necessary to keep this rule language to assure that a record of all medication errors and effects of medication errors on residents is readily accessible. This information can be used by the quality assurance committee to evaluate the kinds of errors that occur in the nursing home and to determine if there are any individual staffing concerns related to the errors. The newly proposed language was developed in response to comments from workgroup members providing suggestions for revisions to the rule language. This revision has been included because it relates to proposed items A and B.

4658.1325 ADMINISTRATION OF MEDICATIONS.

The proposed 4658.1325, subpart 1, would be new language in these state licensing rules. It is patterned after federal certification language. Compliance with this proposed language would not pose a problem for 99% of the nursing homes because they are certified and are already required to have these services. Six of the seven licensed only nursing homes who responded to a questionnaire already have pharmacy consultants, and five of these nursing homes already do monthly drug reviews. It is necessary to include this language in the proposed rules to ensure systematic procedures for handling all aspects of medications. It is reasonable to include this language because it is a safety mechanism for both staff and residents.

The proposed language in subpart 2 is a revision of the current part 4655.7700, subpart 2. Current language in subpart 2 addresses who is allowed to administer medications during an 8 hour shift. The proposed language is necessary to clarify the intent of the language. The Nurse

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

Proposed language in subpart 3 is a revision of the current part 4655.7700, subpart 3. The requirement for attaining the age of 18 has been deleted. It is reasonable to delete this age reference because qualifications and character are a more important factor to use in determining if a person may administer medications than age alone. It is reasonable to require a list of authorized staff who may administer medications to ensure that those in charge are knowledgeable of which staff in the nursing home are authorized to administer medications.

Language proposed in subpart 4 has been developed in response to comments from workgroup members providing suggestions for revisions to the rule language. The proposed language is reasonable because it corresponds with and enhances resident rights.

Language proposed in subpart 5 is a revision of the current part 4655.7700, subpart 4. The current 4655.7700, subpart 4 has been revised by adding the terms "physician's assistant" and "nurse practitioner" to the rule. It is necessary to include these terms in the proposed rule because it clarifies those persons other than nursing home staff who are able to give injections. The addition of "self-administered by a resident" is new language developed in response to comments from workgroup members providing suggestions for revisions to the rule language. This proposed language is reasonable because it corresponds with and enhances resident rights.

Language proposed in subpart 6 is a revision of the current part 4655.7700, subpart 5. The current 4655.7700, subpart 6 has been revised by adding a requirement for a physician's order and resident consent prior to adding medication to a resident's food. It is necessary and reasonable to include this language because it ties in with resident rights. This proposed rule would not prohibit mixing medication with applesauce, jelly, pudding, or other similar substance for the purpose of swallowing the medication.

The proposed subpart 7 is a revision of the current part 4655.7700, subpart 9. It contains grammatical changes updating "patient" to "resident" and deletes the requirement for "recording medications on the chart".

Proposed language in subpart 8 is a revision of current parts 4655.7760, subpart 1 and 4655.3900, subpart 2. Although many of the Steering Committee and workgroup members expressed a concern for being able to document the administration of a medication prior to or at the time of its actual administration, the Department believes that it is necessary for the documentation of medication administration to be done AFTER it is administered. Because the medication record is a legal document, it is necessary to record each medication as soon as possible after the medication is given. Documentation prior to administration even if done immediately prior to the administration would indicate that a resident received a medication when that is not actually true. It is necessary for documentation of medications to occur

immediately after they are administered to avoid any potential for a duplicate dose to be given. Recording medications prior to administration is unethical and can create a potential for needing to alter a legal document. The current standard of practice is to document medications, treatments and observations after they have occurred.[25],[26],[27],[28],[29]

In 1987, a waiver was requested by a nursing home for current part 4655.7700, subpart 9, which was denied. A hearing was subsequently held at which the Administrative Law Judge (ALJ) also recommended denial of the waiver. The ALJ stated that there were increased occasions for nursing errors when pre-charting is done and that complying with the current rule would not place a burden on the facility. Refer to the Matter of St. Anthony Eldercare on Main, docket #9-0900-1695-2, Findings of Fact, Conclusions and Order, November 6, 1990.[30],[31]

4658.1330 WRITTEN AUTHORIZATION FOR ADMINISTERING DRUGS.

The proposed part 4658.1330, revises the current part 4655.7710 by deleting the term "licensed physician or dentist" and updating the language to reflect current practice. Nursing practitioners and physician assistants are also authorized to write certain kinds of orders, so it is necessary to include these individuals in the proposed rules.

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

[26] Norton, B., Miller, A., "Skills for Professional Nursing Practice: Communication, Physical Appraisal, and Clinical Techniques," Appleton-Century-Crofts, 1986:842. (Note: this publication is now out of print.)

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

[28] Loeb, S., editor, "Nursing Procedures," Springhouse Corp., 1992:214.

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

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

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

The current rule requiring telephone orders to be signed within seven days has also been deleted. Nursing homes are not always able to get telephone orders back from the physician or dentist within seven days. It is reasonable to make the proposed language more realistic by requiring telephone orders to be signed "at the time of the next visit" as required at 4658.0455.

4658.1335 DRUGS IN STOCK.

The proposed part 4658.1335, subpart 1, is a revision of current part 4655.7720, subpart 6. The last sentence of current subpart 6 has been deleted and proposed language now says that the stock supply of medications must be kept in the original container. This language is needed to ensure that the medication is identifiable to the point of administration, which allows for safer distribution of the medications because most labels on original containers include dosage, directions and an expiration date.

Proposed subpart 2 is a revision of current 4655.7720, subpart 7. Current language requires a physician to authorize a minimum supply of emergency medications and assume responsibility for this emergency supply. The proposed revisions are necessary and reasonable because they would strengthen the coordination of federal and state regulatory language. Proposed language located in part 4658.0070 requires a quality assurance and assessment (QAA) committee to approve this emergency drug supply. Federal certification language requires a quality assessment and assurance committee to meet quarterly to identify issues with respect to which quality and assurance activities are necessary. This committee is responsible for identifying issues that necessitate action of the committee, such as those issues which negatively affect quality of care and services provided to residents. In addition, the committee is responsible for developing and implementing plans of correction for purposes of correcting identified quality deficiencies in areas such as pharmaceutical services. The newly revised Board of Pharmacy rules (Minnesota Rules, Chapter 6800) also require a quality assurance and assessment committee to determine the emergency drug supply. Those rules also require the emergency drugs to be the property of the pharmacy so it is also reasonable to specify in the proposed rule that pharmacies assume the responsibility of the contents of the emergency drug supply. It is reasonable to reference part 6800.6700 which is in the Board of Pharmacy rules for further clarifications rather than repeating requirements in this proposed rule. Other parts of the current rules have been deleted or are included elsewhere in these proposed rules.

The proposed subpart 3 is a revision of current 4655.7720, subpart 8. It contains new language developed in response to comments from workgroup members providing suggestions for revisions of the rule language. This language states that prescription drugs for one resident may not be used for another resident "except in an emergency". This proposed language is necessary because it allows nursing home staff to "borrow" a medication from one resident when the same medication is needed for another resident and is not immediately available from the pharmacy. The proposed language also incorporates an area of monitoring by the QAA committee as a requirement. This area of monitoring is necessary and reasonable to assure that a system is developed and implemented to replace borrowed medications so that residents receive medications they have paid for.

4658.1340 MEDICINE CABINET AND PREPARATION AREA.

The proposed part 4658.1340 is a revision of current part 4655.7730. Several of the current rules outlined in the current part 4655.7730 are outdated and do not currently reflect what is going on in nursing homes in the area of medication storage and preparation. Language in proposed subpart 1 matches federal certification language. It is necessary to require that drugs be kept in locked compartments in the proposed language to ensure that residents or unauthorized persons are unable to obtain access to the medications. Proposed language to keep drugs at proper temperatures is reasonable to ensure that the identity, strength and quality of the drug are not adversely affected. The proposed language permitting only authorized personnel to have access to keys which unlock compartments containing drugs is necessary to ensure that unauthorized personnel do not have access to these drugs.

Proposed language for subpart 2 is patterned after federal certification language. It is necessary and reasonable to expect that Schedule II drugs be locked in separate, permanently affixed compartments because these drugs have a high potential for abuse and need the additional security offered in this proposed rule. While other controlled drugs can also be abused, the nursing home should have a system in place detecting the disposition of these other controlled drugs as stated in 4658.1350.

4658.1345 LABELING OF DRUGS.

The language proposed at 4658.1345 is a revision to current 4655.7750. The proposed language is patterned after federal certification language. It is necessary and reasonable to update this language to make it consistent with other state and federal laws.

4658.1350 DISPOSITION OF MEDICATIONS.

Proposed language for 4658.1350 is a revision of current parts 4655.7780 and 4655.7760, subpart 3. Language in proposed subpart 1 is a revision of 4655.7780, subpart 1, item A. The proposed language deletes the requirement "if authorized by the attending physician or the physician in charge" and contains some grammatical changes updating the term "patient" to "resident" and "patient's chart" to "clinical record". It is necessary and reasonable to specify in rule that medications must be given to residents when discharged or transferred because the resident has already been authorized by the physician to have this medication and the medication is the resident's personal property. It is the responsibility of the nursing home to develop policies and procedures for handling the medications of residents who have been transferred or discharged.

Proposed language for 4658.1350, item B is a revision of current 4655.7780, subpart 1, item B. Current item B was revised by adding "or the facility's consulting pharmacist" to persons who may be contacted for the necessary forms. Current part 6800.6500, subpart 3 (Board of Pharmacy Rules) requires the Board of Pharmacy to supply the necessary instructions and forms. It is reasonable to add language to our proposed rules regarding the consulting pharmacist because it clarifies for nursing homes that the consulting pharmacists would already have these forms and it may be easier for the nursing home to obtain these forms from the consulting

pharmacist than from the Board of Pharmacy. This does not mean that the nursing home must contact the Board of Pharmacy or consulting pharmacist each time unused portions of controlled substances are disposed but rather that the nursing home could have a supply of necessary forms available and would only need to contact the Board of Pharmacy or consulting pharmacist when additional forms are needed.

The proposed item C is a revision of current part 4655.7780, subpart 1, item C. The proposed language deletes the requirement that the "supervising nurse" will destroy unused portions of prescription drugs. This proposed language would change "supervising nurse" to "nursing staff in the presence of a registered nurse or pharmacist". The steering committee wanted the term "nursing staff" used in place of "supervising nurse" to give more flexibility to the nursing home in deciding who could do drug destruction. It is reasonable to allow the facility the flexibility to have "nursing staff" dispose of unused drugs. Nursing home policies and procedures would determine which staff are authorized to destroy unused drugs. Additional language of "in the presence of a registered nurse or pharmacist" was added by the Department to make the rule more compatible with the Board of Pharmacy Rules which requires that the unused drugs be destroyed by the facility in the presence of a pharmacist or registered nurse. It is necessary to add the requirement that a registered nurse or pharmacist must be present because it clarifies who must witness the destruction of unused drugs and the language is in concert with Board of Pharmacy rules.

Proposed item D contains grammatical changes from the current rule 4655.7780, subpart 1, item D. In addition to the grammatical changes, "or disposition" and witnessed "as specified in 4658.1350, item C" was included in proposed rule language. This language is needed to clarify who is responsible to witness the destruction or disposition of unused drugs. It is reasonable to include this language to assure that specific information is included in the clinical record.

The language in proposed subpart 2 is a revision of current part 4655.7760, subpart 3. The proposed language deletes the current requirement for entering a controlled substance into the resident's record when it is given and having the supervising nurse sign and record the narcotic count at least once every day. Documentation of medications is covered elsewhere in these proposed rules and does not need to be repeated here. It is also not necessary to require the frequency that staff record and sign a narcotic count. By deleting this current requirement, the nursing home is given the flexibility to determine the method that will best meet its needs and serve its residents and the freedom to develop its own system. The inclusion of language from current part 4655.7760, subpart 3 is necessary and reasonable because it strengthens the intent of the federal certification language providing for appropriate control of Schedule 2 drugs.

Proposed subpart 3 is a revision of current 4655.7780, subpart 2. The proposed language deletes "other than controlled substances" from the current requirement. It is necessary to delete "other than controlled substances" from the proposed rule because the Board of Pharmacy prohibits the return of controlled substances. This does not need to be repeated in these proposed rules. The current requirement of in accordance with "the provision of the Minnesota Board of Pharmacy" was also deleted from this proposed rule. It is reasonable to specify in the proposed rule which Board of Pharmacy rule to refer to. This reference makes it easier for nursing homes to find exact information pertaining to the return of drugs.

4658.1355 MEDICATION REFERENCE BOOK.

Proposed 4658.1355 is a revision of current 4655.7790, subpart 2. It is necessary to require a current (meaning the latest published edition) issue of one or more medication reference books. The nursing home would be responsible for maintaining a book of medication references that includes medications used in the nursing home to assure that staff are able to research a medication if they are unfamiliar with the medication. The current requirement for "maintaining current medication references such as the ASHP Hospital Formulary Service" is no longer necessary to include in rule language. The important issue is that staff in the nursing home are provided with references that will answer their questions. It is reasonable to allow the nursing home to decide which reference books are appropriate for their use. Current subpart 1 was deleted in these proposed rules because the Board of Pharmacy prohibits a pharmacy to operate without a license.

4658.1360 ADMINISTRATION OF MEDICATIONS BY UNLICENSED PERSONNEL.

The proposed 4658.1360, subparts 1 and 2 are a revision of current 4655.7860. The proposed language deletes the current requirement pertaining to unlicensed nursing personnel who administer medications in a boarding care home certified as an intermediate care facility because this requirement is not relevant to these proposed rules for nursing homes. Access to postsecondary educational institutions can be difficult in some areas of the state so it is necessary to include language allowing nursing homes to develop their own medication administration training programs to help alleviate this problem. It is reasonable to include specific areas of education that need to be covered in medication administration training programs, especially for nursing homes that opt to do their own medication administration training programs to ensure that all aspects of medication administration training is done. This proposed language is based on language proposed at 4658.1325.

Proposed subpart 3 contains new language developed in response to comments from workgroup members and the Steering Committee providing suggestions for revisions to the rule language. Proposed language refers to which types of medications may be administered by unlicensed personnel and under what circumstances this would be allowed. Pro re nata medications must be reported to a registered nurse prior to administration to a resident because the Nurse Practice Act specifies that only a registered nurse has the direct statutory authority to delegate to others. This is not a function that a licensed practical nurse may do. This should not pose a problem because both current and proposed rules require a registered nurse to be on call during all hours when a registered nurse in not on duty. It is necessary to specify this information because it clarifies medication administration issues.

4658.1365 PENALTIES FOR MEDICATION AND PHARMACY SERVICES.

See the discussion in part 4658.0045, above.

Some parts of this section of proposed rules are not significantly different from current rule language. The proposed fines for non compliance with those sections are the same as those for the comparable sections in the current rules. This includes the fines for proposed parts 4658.1325, subparts 1, 2, 3, 5, 7, and 8; 4658.1330; 4658.1335; 4658.1340; 4658.1345;

4658.1350; 4658.1355; and 4658.1360, subparts 1 and 2.

The fines for noncompliance with correction orders for parts 4658.1305 through 4658.1320; 4658.1325, subparts 4 and 6; and 4658.1360, subpart 3 have been established in accordance with the 8 tier level of fines developed to correlate with the impact of noncompliance on the resident.

Part 4658.1305 addresses the services to be obtained from pharmacists. The proposed fine for noncompliance with this part is set at $300, the penalty assessment for rules that are necessary to ensure that services are properly provided. This amount is reasonable because noncompliance with these rule parts would affect the quality of pharmacy services that is provided to residents. Compliance with this rule is necessary to assure that the actual provision of pharmacy services is done is a safe and effective manner.

The penalty assessment for noncompliance with correction orders addressing part 4658.1310 is set at $300, the level which is assigned to those rules necessary to ensure that services are properly provided by the nursing home. This amount is reasonable because noncompliance with these rule parts would result in inadequate drug reviews, which could have a negative impact on the resident. Compliance with these rule parts is necessary to ensure that safe and effective drug therapy is available to residents.

The fines for noncompliance with correction orders for part 4658.1315 is also set at $300 for the same reasons stated above. It is reasonable to set this amount to ensure that adequate monitoring for unnecessary drugs takes place. Noncompliance with these rules would result in the inability to adequately meet the needs of the residents.

Part 4658.1320 addresses medication errors. The proposed fine for noncompliance with this part is set at $500. This level of fine is assigned to those rules that present an imminent risk of harm to the health, treatment, comfort, safety,. or well-being of nursing home residents. This amount is reasonable because noncompliance with these rule parts could present an imminent risk of harm as listed above to nursing home residents. The maximum fine is necessary and appropriate to protect the health and well-being of nursing home residents.

The fine for noncompliance with correction orders for part 4658.1325, subpart 4 is set at $250. This is the penalty assessment assigned to those rules that relate to the protection of the individual rights of residents. This amount is reasonable because noncompliance with this rule part would affect resident rights pertaining to self-administration of medications. Compliance with this rule is necessary to ensure that residents are involved in determining care needs.

The fine for noncompliance with correction orders for part 4658.1325, subpart 6 is also set at $250. It is reasonable to set this amount because noncompliance with this rule would directly affect resident rights. Compliance with this rule is necessary to ensure resident involvement and decision making pertaining to taking medications.

The penalty assessment for noncompliance with correction orders addressing part 4658.1360, subpart 3 is set at $350, the penalty assessment for rules that are related to the direct provision of services to residents. This rule directly relates to the provision of administering certain

categories of medications to residents. This amount is reasonable because noncompliance with these rule parts would affect the service of medication administration to residents. Compliance with the rule parts is necessary to assure the safe provision of medications to residents.

REPEALED PARTS OF CHAPTER 4655

Certain parts of the current chapter 4655 would be repealed upon promulgation of these proposed parts of chapter 4658. The repealing would be done because parts of chapter 4658 would replace or supersede those parts of chapter 4655; these are parts of chapter 4655 which currently apply only to nursing homes, and not to boarding care homes. The intent is to eventually locate all the nursing home licensing rules in chapter 4658, and leave all the boarding care home licensing rules in chapter 4655.

Parts 4655.2410, Use of Oxygen, and 4655.2420, Standards for the Use of Oxygen, would be repealed, to be replaced by the proposed part 4658.0090, Use of Oxygen.

Part 4655.3900, Nurses' Record would be repealed, to be replaced by the proposed parts 4658.0110, 4658.0450, and 4658.0515.

Part 4655.4900, Admissions and Telephone Orders in Nursing Homes, would be replaced by the proposed parts 4658.0455 and 4658.0710, subpart 2.

Part 4655.5600, Nursing Staff, 4655.5700, Director of Nursing Service, 4655.5800, Responsibilities of the Director of Nursing Service, 4655.5900, Rehabilitation Nursing Care, 4655.6000, Patient Care Plan, and 4655.6100, Assistance With Eating, would be replaced by the proposed parts 4658.0500, 4658.0505, 4658.0510, 4658.0515, 4658.0525, and 4658.0530.

Part 4655.6200, Educational Opportunities, would be repealed and replaced with the proposed parts 4658.0100 and 4658.0525, subpart 10.

Part 4655.6800, Patient Care, would be repealed and replaced with the proposed parts 4658.0520 and 4658.0525.

Part 4655.7600, subpart 1, would be repealed because it becomes unnecessary.

Parts 4655.7700, 4655.7710, 4655.7720, 4655.7730, 4655.7740, 4655.7750, 4655.7760, 4655.7770, 4655.7780, and 4655.7790 (all dealing with medications) would be repealed, and replaced with the proposed parts 4658.1300, 4658.1305, 4658.1310, 4658.1315, 4658.1320, 4658.1325, 4658.1330, 4658.1335, 4658.1340, 4658.1345, 4658.1350, 4658.1355, and 4658.1360.

Part 4655.8100, Sanitizing of Nursing Utensils, would be repealed and replaced with the proposed part 4658.0800.

Part 4655.9400 would be repealed because the statute requiring the establishment of a time period for complying with a correction order has been repealed.

TECHNICAL CHANGES TO MINNESOTA RULES CHAPTER 9050

Minnesota Rules, Chapter 9050 govern the operation of the Minnesota veterans homes, which are owned or controlled by the state of Minnesota and operated by the Minnesota Veterans Homes Board. Parts 9050.0010 to 9050.0900 establish the standards to be used to determine:

A. an applicant's eligibility and suitability for admission to a board-operated facility;
B. a resident's eligibility for participation in programs at a board-operated facility;
C. appropriateness of a resident's continued care in a board-operated facility;
D. services to be provided in connection with residence in a board-operated facility;
E. procedures to be used in effecting admissions and discharges;
F. standards of resident care and conduct; and
G. charges to be paid by or on behalf of a resident for care in the home.

Portions of the nursing home licensing regulations, found in Minnesota Statutes, sections 144.50 to 144.56 and 144A.02 to 144A.10, and Minnesota Rules, chapters 4655 and 4660, are cited in chapter 9050.

Those sections of chapter 9050 that include a citation to a part in chapter 4655 that is being superseded for licensed nursing homes by a part in the proposed chapter 4658 will be amended upon the promulgation of chapter 4658. This includes parts 9050.0210, subpart 2, 9050.1030, subparts 1 and 16, and 9050.1070, subpart 25. The only changes to these parts of Chapter 9050 are the inclusion of the applicable part of Chapter 4658 in the citation to the nursing home licensing rules.

TECHNICAL CHANGE TO MINNESOTA RULES CHAPTER 9505

Minnesota Rules, parts 9505.0170 to 9505.0475 govern the administration of the medical assistance program, establish the services and providers that are eligible to receive medical assistance payments, and establish the conditions a provider must meet to receive payment.

Part 9505.0390, Rehabilitative and Therapeutic Services, includes a reference to part 4655.5900, subparts 2 and 3. Part 4655.5900, subparts 2 and 3 address rehabilitation nursing care in licensed nursing homes. With the promulgation of these proposed rules, part 4655.5900 will be repealed. The proposed part 4658.0525 addresses rehabilitative nursing care, and will replace 4655.5900.

Part 9505.0390 will be revised to include the reference to the proposed part 4658.0525.

STATEMENT OF ANTICIPATED COSTS AND BENEFITS

Minnesota Statutes § 144A.29, subdivision 4 (1993) states that:

> *Each rule promulgated by the commissioner of health pursuant to sections 144A.01 to 144A.15 shall contain a short statement of the anticipated costs and benefits to be derived from the provisions of this rule.*

This law requires that the Department of Health estimate the cost that a nursing home will incur as a result of the promulgation of the rules. This cost estimate must also be accompanied by an explanation of the benefits that will result from the new rules. This analysis will be helpful in ascertaining the total costs of the rules.

Since a substantial portion of the nursing home costs are covered by the Medicaid program this statement will also be helpful in determining to what extent the rules will impact on the cost of the Medicaid program.

GENERAL COMMENTS ON THE ANTICIPATED COSTS AND BENEFITS

Licensed nursing homes and boarding care homes wishing to participate in the federal Medicare or Medicaid programs must comply with the federal regulations known as "Requirements for Participation." Nursing homes and boarding care homes are "certified" for participation in the Medicare or Medicaid programs when they are found, through onsite surveys, to be in compliance with the federal Requirements for Participation. Approximately 99% of nursing homes in Minnesota are certified to participate in one or both of those federal programs.

A number of rules being proposed at this time will not have a cost impact on nursing homes. Many of the proposed rules relating to health services in licensed nursing homes either correspond directly or very closely to current rule language, or match the existing federal certification language. This means that approximately 99% of the nursing homes in Minnesota (the licensed and certified facilities) are already complying with similar regulatory language, and the reimbursement rates established under the Medicaid program address the costs of meeting those requirements. The licensed-only (non-certified) nursing homes have indicated that they generally provide services of at least the same level as the certified nursing homes because that is the standard by which consumers judge them. So, the promulgation of these proposed rules will likely have little or no financial impact on most of the non-certified nursing homes.

SPECIFIC RULE PROVISIONS

Licensing

4658.0010 DEFINITIONS
4658.0015 FORWARD
4658.0020 LICENSING IN GENERAL

4658.0025 PROCEDURES FOR LICENSING NURSING HOMES
4658.0030 CAPACITY PRESCRIBED
4658.0035 EVALUATION
4658.0040 VARIANCE AND WAIVER

There are no anticipated costs of implementing these proposed rule parts because they contain language currently in rule which licensed nursing homes are required to comply with. There are basically only editorial differences between the current rules and these proposed rules. The benefits of these rules are the establishment of definitions for rule terminology, to specify the procedures to be followed for the licensing process, setting capacities of nursing homes, clarifying when nursing homes need approval from the Department of Health when they are changing the physical plant or services, and the procedures to follow for requesting and granting variances and waivers to these rules.

4658.0045 PENALTIES FOR LICENSING

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders.

Administration

4658.0050 LICENSEE
4658.0055 ADMINISTRATOR
4658.0060 RESPONSIBILITIES OF THE ADMINISTRATOR
4658.0065 RESIDENT SAFETY AND DISASTER PLANNING
4658.0070 QUALITY ASSESSMENT AND ASSURANCE COMMITTEE
4658.0075 USE OF OUTSIDE RESOURCES

There are no anticipated costs of implementing these proposed rule parts because they contain language currently in rule which licensed nursing homes are required to comply with. There are basically only editorial differences between the current rules and these proposed rules. The benefits of these rules are to specify the duties and responsibilities of the licensee and the administrator, require a written safety program and disaster plan to prevent unsafe conditions and protect residents and staff in case of an emergency, to have a committee convened to improve the quality of care provided to residents, and to require all persons providing services in the nursing home to meet the standards and requirements of these rules, in order to protect the health, safety, comfort, treatment, and well-being of the residents.

4658.0080 NOTIFICATION OF BOARDS

There are no anticipated costs associated with this new provision in the state licensing rules for nursing homes because they can meet this requirement using existing staff to notify the applicable professional board. The benefits of this proposed part are to protect the health, safety, comfort, treatment, and well-being of the residents who are receiving services in that nursing home.

4658.0085 NOTIFICATION OF CHANGE IN RESIDENT HEALTH STATUS

There are no costs associated with this proposed rule part, which is a revision of current rule language and incorporates federal certification language. Nursing homes are already required to notify physicians and family in case of acute illness or serious accident to a resident, and

notify physicians immediately of apparent resident deaths. The benefits of the proposed language relate to staff resources and communications with providers and residents' families. The revised language may actually save costs, improve notification times, and assuage communications by requiring the nursing home to have already established policies of when and whom to contact when there is a change for the worse in the resident's condition. Nursing home staff will not need to ponder and ask questions about notifying persons - there will already be a written policy to follow.

4658.0090 USE OF OXYGEN
4658.0095 AVAILABILITY OF LICENSING REGULATIONS
4658.0100 EMPLOYEE ORIENTATION AND INSERVICE EDUCATION
4658.0105 COMPETENCY
4658.0110 INCIDENT AND ACCIDENT REPORTING
4658.0115 WORK PERIOD
4658.0120 EMPLOYEE POLICIES
4658.0125 PERSONAL BELONGINGS
4658.0130 EMPLOYEES' PERSONNEL RECORDS

There are no anticipated costs of implementing these proposed rule parts because they contain language currently in rule which licensed nursing homes are required to comply with. There are basically only editorial differences between the current rules and these proposed rules. The benefits of these rules are to establish minimum standards for nursing home employees - their training, qualifications, responsibilities, and personnel management, to ensure that there are qualified staff, and that basic occupational and business requirements necessary for the efficient operation of the nursing home are maintained.

4658.0135 POLICY RECORDS

There are no costs associated with the language in the proposed 4658.0135, subpart 1, which is a revision of current language at 4655.4200 because the nursing home is already expected to have the policies and procedures on file. There should be no additional costs to make those written policies and procedures available to residents and family members, as well as to facility personnel. The benefits of adding additional persons to those who may view the nursing home's policies and procedures are to increase the knowledge base of residents and families as to how the nursing home operates, what its operating philosophy is in terms of how it addresses situations or problems, and what standards are established for that nursing home. This empowers the consumers, and allows for improved communications and expectations between residents and family and the nursing home.

There are no costs associated with the proposed 4658.0135, subpart 2, again because the nursing home will already have admission policies on file and so can make them available upon request. The benefits are improved customer relations and potentially more suitable placements for some residents - consumers would be able to get a better understanding of the policies, procedures, and services offered at a nursing home and so could make a more informed decision about the selection of a nursing home.

4658.0140 TYPE OF ADMISSIONS

There are no costs associated with the language in the proposed part 4658.0140 because it is an

updating of the language currently found at part 4655.1500. The benefits of requiring nursing homes to have developed policies for admission, and to be aware of what services it can provide to residents, is the clarification of its mission to prospective residents and to the nursing home, and the assurance that the resident will receive the necessary services at the place of admission.

4658.0145 AGREEMENT AS TO RATES AND CHARGES

There are no anticipated costs associated with the proposed 4658.0145, subpart 1, since it is existing rule language. There are no anticipated costs associated with the proposed 4658.0145, subpart 2, first because it matches federal certification language which 99% of the licensed nursing homes in Minnesota already must comply with, and secondly because those few licensed only nursing homes are already providing a notification to residents of changes in rates. The nursing homes either have their rates set at least annually through the case mix reimbursement system or have their rates set by some other method; notifying residents annually and at any changes can be done by existing staff and through existing channels or methods of communication.

4658.0150 INSPECTION BY DEPARTMENT
4658.0155 REPORTS TO THE DEPARTMENT

There are no anticipated costs associated with the implementation of the proposed parts 4658.0150 and 4658.1055 because they contain existing rule language.

4658.0160 PENALTIES FOR ADMINISTRATION AND OPERATIONS

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders.

Restraints

PART 4658.0300 USE OF RESTRAINTS

There are no anticipated costs of implementing this part since the proposed language is a revision and clarification of current state rule language, and incorporates proposed federal certification language. Nursing homes in Minnesota are already expected to be meeting the intent of this proposed rule part addressing the use of restraints. The benefits of adding this language to state rules is to provide clarification and strengthening of resident rights in the area of restraint usage, and to add protections to residents by clearly stating the standards by which restraint use may be conducted and must be evaluated. Restraint use directly impacts on the health, safety, treatment, comfort, and well-being of residents.

PART 4658.0350 PENALTIES FOR USE OF RESTRAINTS

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders. The benefits of having a rule part addressing penalty assessments include the assurance to consumers that there is an incentive to nursing homes to comply with the regulations, and the provision of a clear statement to nursing homes and to government regulators of the penalty for noncompliance with each rule part.

Comprehensive Resident Assessment and Plan of Care

PART 4658.0400 COMPREHENSIVE RESIDENT ASSESSMENT

The language being proposed in this part incorporates current federal certification language. Therefore, for the 99% of the licensed nursing homes in Minnesota which are also certified to participate in the federal Medicare and Medicaid programs, there will be no additional costs associated with implementing this proposed language. Minnesota has a case mix reimbursement system, which requires a resident assessment at admission and periodically throughout the stay in a nursing home. The required elements of the state case mix assessment do not differ greatly from the elements of the federal comprehensive assessment.

The benefits of adding this language to the state licensing rules is the enhancement of the coordination of the federal and state regulations, and the incorporation into the state regulations of the concept of a continuity of: assessment of resident needs, planning for cares to meet resident needs, providing cares, assessment of cares provided and resident needs, adjusting plans for care, and so on. This provides assurance to the resident that they will be receiving the appropriate cares to meet their needs throughout their stay in the nursing home.

PART 4658.0405 COMPREHENSIVE PLAN OF CARE

There are current state and federal requirements for a plan of care, so there should be no costs associated with the promulgation of this proposed rule part. The benefit of this proposed part is the assurance to the resident that the nursing home will develop a plan for providing the necessary cares to that resident, addressing their medical, nursing, mental, and psychosocial needs. This plan will be reviewed by all personnel involved in the care of the resident, so the various disciplines or services are to be aware of what each other are doing. And the plan of care is updated as the condition of the resident changes, so the resident can be assured that the cares they are receiving are appropriate for their current condition.

PART 4658.0420 PENALTIES FOR COMPREHENSIVE ASSESSMENT AND PLAN OF CARE

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders. The benefits of having a rule part addressing penalty assessments include the assurance to consumers that there is an incentive to nursing homes to comply with the regulations, and the provision of a clear statement to nursing homes and to government regulators of the penalty for noncompliance with each rule part.

Clinical Records

PART 4658.0430 HEALTH INFORMATION MANAGEMENT SERVICE

Subpart 1: Although the proposed requirement for a "health information management service" does not exist in current state or federal regulations, there are no anticipated costs associated with this language because the principles listed in the proposed language are in current state and federal regulations, and are derived from current standards of practice among professionals in the field of clinical records management. The activities should already be performed by the

nursing home. The current federal certification language requires the maintenance of "clinical records on each resident in accordance with accepted professional standards and practices". The benefits to requiring a service include the more efficient, appropriate, and secure handling and processing of resident information; in other words, better protection of resident rights to confidentiality of information and the receipt of appropriate services based on their documented needs and choices.

Subpart 2: There may be some costs to some nursing homes to develop and utilize a mechanism for auditing the quality of its health information management service. However, since certified nursing homes are currently required to have a Quality Assessment and Assurance Committee [at 42 CFR 483.70(o)], and since this is a topic which would appropriately be addressed by that Committee, most nursing homes in Minnesota are likely to already be in compliance with this proposed rule. These proposed rules would also require the nursing home to establish a quality assessment and assurance committee (under the proposed part 4658.0070). Benefits of this requirement include ensuring the accuracy, organization, legality, and completeness of the clinical records; auditing for the quality of the information would be a relatively minor activity which can realistically be expected to be performed by current nursing home staff.

Subpart 3: Although there is no current requirement for a person to be designated as responsible for management of the health information collected and maintained by a nursing home, in practice there is currently someone assigned that responsibility. There are no anticipated costs associated with this proposed rule part because this function is already being performed. The benefits of this proposed language is the assurance that there be a person designated as responsible for health information management, which enhances the quality and availability of the information and the value of that information.

PART 4658.0435 CONFIDENTIALITY OF CLINICAL RECORDS / INFORMATION

Subpart 1: This subpart is necessary to implement the statutory requirements for confidentiality of health care records found in Minnesota Statutes, § 144.651 and § 144.335, and to state in rule that representatives of the Department of Health have access to clinical records in order to ascertain the appropriateness of the cares being provided to residents and whether the facility is in compliance with state and federal requirements. There are no anticipated costs of implementing this proposed subpart since these are current requirements. The benefits of this proposed language are the clarification of the requirements for confidentiality of resident information, which is a basic resident right, and the allowance for the availability of that information to pertinent nursing home staff and representatives of the Department of Health, to ensure the resident needs and receives appropriate cares and services.

Subpart 2: There are no anticipated costs of implementing this subpart of the proposed rules. The requirement for development and implementation of policies and procedures if the nursing home chooses to use a facsimile (fax) machine to receive or transmit health care data can be met through the use of existing nursing home employees. This requirement is a standard of practice in the health information management profession. The benefits of this proposed subpart are the assurance to residents that confidentiality and security will be maintained for the information received or sent on a fax machine, and the specification to residents and staff of relevant issues to consider when deciding to use a fax machine.

PART 4658.0440 ABBREVIATIONS

Although this is new proposed language, there are no anticipated costs associated with its implementation. Many nursing homes already have some sort of explanation key, or legend, for the symbols and abbreviations used in the clinical records. This is a standard of practice for many health information management groups. If a nursing home does not currently have an explanation key, it is relatively simple to develop one based on the commonly written abbreviations and symbols generally used in that nursing home (or in the health care industry in that town or provider organization). This can be done by current facility staff. The benefits of having a standardized set of abbreviations and symbols can be profound in terms of the continuity of care which can be provided if all disciplines or services entering documentation into the resident record can understand the terms being abbreviated or symbolized. There was anecdotal evidence provided during workgroup meetings about some relatively common abbreviations which mean entirely different things to different services. By standardizing the documentation, there is greater protection for residents.

PART 4658.0445 CLINICAL RECORD

Subpart 1: Since there are current state and federal requirements for a clinical record for each resident there are no anticipated costs associated with this requirement. The benefits of a clinical record are the availability of information for all providers and practitioners, the provision for continuity of care, to enable providers to evaluate the appropriateness and effectiveness of treatments and services, to facilitate billing, and to provide documentation for survey and compliance purposes.

Subpart 2: There are no anticipated costs since the proposed language is based on current state and federal requirements. The benefits to requirements for form of entries and authentication are the assurances that the information is correct and thorough, the entries can be verified, and it is clear who made each entry.

Subpart 3: There are no anticipated costs to this proposed language because it is based on current standards of practice and upon interpretive guidelines to federal certification language. The benefit is accurate and thorough medical information in the record.

Subpart 4: There are no costs associated with the proposed language because the admission information items listed are all currently gathered by the nursing home on each resident, based on current state and federal requirements. The benefits of this rule are the specification of resident identification information, which will be used by the nursing home to provide cares and services, to contact relatives or other persons, and to enable billing for services.

PART 4658.0450 CLINICAL RECORD CONTENTS

There are no anticipated costs associated with the proposed language because the items to be included in the resident's clinical record are in current state and federal regulations (although they have been found in a number of different parts, and are now proposed to be grouped in this one part). The benefits of the proposed language include matching federal certification language and clustering all the data which is appropriately to be contained in the clinical record so that data is readily available to providers, consumers, and regulators.

PART 4658.0455 TELEPHONE AND ELECTRONIC ORDERS

There are anticipated cost savings associated with the proposed language in this part. Item A merely references applicable statutes addressing confidentiality of records which also apply to orders received by electronic means. Current rules require orders received by the nursing home over the telephone to be countersigned by the physician within 7 days. The proposed language in item B eliminates that 7-day requirement, replacing it with "at the time of the next visit." This change is expected to save the nursing homes significant time and energy, as well as postage and mileage. Since they currently are required to get those countersignatures within the 7 days, staff must often go to the doctor's office or otherwise track down the doctor for signatures in order to meet that timeframe. Item C requires faxed orders to have been signed by the ordering physician or dentists (signature on the original); they are not required to then sign the copy of the fax as received by the nursing home. Benefits include clarification of requirements, elimination of irrelevant compliance requirements, and a more logical and workable process for verifying orders received by telephone, fax, computer, or other electronic means.

PART 4658.0460 MASTER RESIDENT RECORD

There are no anticipated costs associated with this part since it is a current requirement (in part 4655.3700) which has been revised to allow for additional methods of maintaining the required information. The benefits of a master resident record are the maintenance of a permanent record of residents admitted to that facility, and the ability to calculate statistics required for reimbursement and regulatory purposes.

PART 4658.0465 TRANSFER, DISCHARGE, AND DEATH

There are no costs associated with this part since it contains current rule language. The benefits of this proposed part include the grouping of requirements for record completion and disposition (currently found at part 4655.3300, subpart 2 and part 4655.3500, subparts 2 and 4). This grouping of related requirements is intended to clarify the regulations by making related topics easier to locate.

PART 4658.0470 RETENTION, STORAGE, AND RETRIEVAL

There are no costs associated with this part since it contains current rule language in subparts 1 and 2. Subpart 3 requires the development and implementation of policies and procedures if nursing homes choose to store records of discharged residents offsite. These can be developed using current nursing home staff; implementation of suitable policies should not result in increased costs, and could be expected to save money in the long run by providing a blueprint for the offsite storage, retention, and retrieval of those records.

PART 4658.0475 COMPUTERIZATION

There are no anticipated costs associated with this proposed part because this is a new section of rules, and nursing homes have not been allowed to have a "paperless" health information management system under current rules. Since this is new, and is an option for nursing homes to choose (not a mandate), it is appropriate to state specific standards for the establishment of an effective, confidential, accurate system. The benefits of the proposed language, which was

developed by health information management professionals, include the development of systems which meet applicable requirements of confidentiality, accuracy, integrity, and security for the clinical records.

PART 4658.0490 PENALTIES FOR CLINICAL RECORDS

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders. The benefits of having a rule part addressing penalty assessments include the assurance to consumers that there is an incentive to nursing homes to comply with the regulations, and the provision of a clear statement to nursing homes and to government regulators of the penalty for noncompliance with each rule part.

Nursing Services

PART 4658.0500 DIRECTOR OF NURSING SERVICES

There are no anticipated costs associated with the implementation of subparts 1, 2, and 3 of this part. The proposed revisions contain the same language as current rules (Part 4655.5700).

There may be some costs associated, and also some savings associated, with the implementation of subpart 4, which would require directors of nursing to have education in more areas than are currently required in state rules (Part 4655.5700, subpart 5). In these proposed rules, this education is to be acquired before or within 12 months after appointment as director of nursing service. The areas which would be added are gerontology, management, and supervision. These topic areas are applied every day by the director of nursing in the normal course of carrying out their responsibilities. By having education in these areas, the director of nursing can be expected to be better prepared for the demands of the job. To maintain their nursing license, nurses are required to receive 24 hours of continuing education every 24 months. These courses will likely dovetail with those continuing education requirements. One of the Major Recommendations from the Minnesota Department of Health's Commissioner's Task Force on Nursing Home Mortality Review Report is:

> "The state should pursue, recommend, adopt, and implement policies designed to help enhance the professionalization of the Director of Nursing role and to increase the tenure of Directors of Nursing in the nursing homes of this state."[32]

There were eight other recommendations relating to identification of management skills and educational programs and requirements for directors of nursing in that report.

While developing the rule revisions, the Department heard many examples of persons being promoted to or hired as director of nursing with little or no preparation for the position other than being a registered nurse; the turnover rate for directors of nursing was said to be extremely high because nurses just were not prepared for the job. Benefits of the proposed additions to

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[32] "Commissioner's Task Force on Nursing Home Mortality Review Report," Minnesota Department of Health, November 1990.

the rule language include lower turn-over rates and better employee satisfaction: by requiring better preparation of these people for this position, it can reasonably be expected that they will have realistic expectations and the skills necessary to function successfully as a director of nursing. By being better prepared, it is likely that they will stay in the position longer, which means there will be lower facility costs associated with filling the position. Courses in gerontology, management, and supervision are widely available throughout the state, and many will provide continuing education credits (CEUs) for the nurses, which are a nurse licensing requirement. Training costs are a reimbursable expense under the state's case mix reimbursement program. The persons currently serving as directors of nursing will be "grandparented" into this rule revision. That is, those persons will not need to meet the new language. Only persons hired as director of nursing after the effective date of these rules would need to have had or receive the appropriate training within 12 months after appointment as director of nursing.

PART 4658.0505 DIRECTOR OF NURSING SERVICE; RESPONSIBILITIES

There are no anticipated costs associated with the implementation of the proposed rules found at 4658.0505 because these are generally all included in current state rules at 4655.5800. They have been updated to include appropriate terminology. The benefit of having this rule part is the specification of the responsibilities of the director of nursing, so that is clear to the nurses themselves, to the nursing home administration and staff, residents and family, and regulators.

PART 4658.0510 NURSING STAFF

There are no costs associated with the implementation of this proposed part since it contains current rule and statutory language.

PART 4658.0515 FREQUENCY OF REPORTING

There are no costs associated with the implementation of this proposed part since it contains current rule language. The benefits of this proposed part are the clarification of documentation frequency and specificity on reporting requirements from which to analyze resident outcomes.

PART 4658.0520 ADEQUATE CARE

For the most part, the proposed language found in 4658.0520 matches that found in current rules. One area which may cause decreased costs, mainly for staff time, is the proposed revision found in subpart 2, item B, which would change the requirement from a minimum of a complete tub bath or shower once a week to a requirement for a bathing plan for each resident. Nursing home staff reported that there is a relatively large amount of staff time spent on some residents who do not wish to have a weekly bath (and who can still have "clean skin and freedom from offensive odors", as the current and proposed language requires). There are methods of keeping the skin clean and free from offensive odors other than a full tub bath or shower, such as sponge baths. Many residents of nursing homes could be at risk of dry skin problems if they have too frequent baths. Also, there needs to be greater consideration of resident choice in the frequency of bathing, as with all areas of cares and services provided. A number of the elderly persons currently residing in nursing homes do not have a tradition of daily or even weekly bathing, and should not have to change their habits just because they are now residing in a nursing home. On the other hand, there are residents who desire or require more frequent bathing or showering than once a week. The requirement for a bathing plan

should better accommodate their choices and needs than simply requiring a weekly bath or shower.

One area which could possibly cause increased costs to nursing homes is the proposed revision found in subpart 2, item C, which would change the requirement from a minimum of monthly shampoos to a minimum of a shampoo every 7 days. There may be some nursing homes which have limited the amounts of shampoos provided to residents to one per month, which meets the current state rule requirement but does not always meet the resident's needs, or satisfy their choices. By revising this rule to require a minimum of a weekly shampoo, the rules will more directly reflect current standards of providing cares and current resident standards for cleanliness and grooming. For those residents for whom a weekly shampoo is too frequent, their care plan and bathing plan would address the desired frequency for shampoos, based on their needs and choices. It can be expected that shampoos are done at the same time as baths or showers, so there is time already built into the scheduling of cares in which to provide shampoos. Most of the people on the public workgroups which addressed this issue related that their facility provides shampoos at the same time as baths or showers so there would not be a significant addition to staff time needing to be spent preparing most residents, nor spent providing the shampoo. Those people reported that their nursing home routinely provides weekly shampoos already, so there will be no additional costs to their nursing home associated with this proposed revision. Expected benefits of this proposed revision include the opportunity for greater resident choice and satisfaction with their hair cleanliness, which can be expected to lead to increased self-esteem and well-being of residents, which may have positive affects on their physical, mental, and psychosocial health.

PART 4658.0525 REHABILITATION NURSING CARE

Subpart 1: There are no costs associated with the implementation of this proposed part since it contains current rule language.

Subparts 2 through 9: These proposed subparts are clarifications of current rule requirements, and incorporate federal certification language into the state rules. The proposed language contains more specificity than current rule language, but there are no costs associated with the revisions because all licensed nursing homes are already expected to comply with the intent of the language, and all certified nursing facilities are already expected to comply with the language itself. The benefits of the revisions are clarification to residents, providers, and regulators, of the expectations of the rehabilitation nursing care to be provided by the nursing home. These include the basic cares which are the most common reasons people need to be admitted to nursing homes. It is appropriate to be specific on what those basic rehabilitation nursing services must include.

Subpart 10: There are no costs associated with the implementation of this proposed part since it contains current rule language.

PART 4658.0530 ASSISTANCE WITH EATING

Subpart 1: There are no costs associated with this subpart because it contains current rule language. The benefits of this subpart include resident protections of health, safety, well-being, and dignity.

Subpart 2: There are no costs associated with this subpart because it contains current rule language and incorporates current policy, based on the findings of an Administrative Law Judge, into rule language. The benefits of this subpart include resident protections of health, safety, well-being, and dignity.

PART 4658.0580 PENALTIES FOR NURSING SERVICES.

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders. The benefits of having a rule part addressing penalty assessments include the assurance to consumers that there is an incentive to nursing homes to comply with the regulations, and the provision of a clear statement to nursing homes and to government regulators of the penalty for noncompliance with each rule part.

Medical and Dental Services

PART 4658.0700 MEDICAL DIRECTOR

Although the proposed requirement for a medical director is not in current state rules, the federal certification language does require certified nursing facilities to have a medical director. As discussed in the Statement of Need and Reasonableness, the Department contacted the noncertified nursing homes to discuss how certain of the proposed rule revisions would affect them. At that time, there were only two noncertified nursing homes which did not already have a medical director, and those two had physicians either on staff or on its Board of Directors which perform many of these proposed responsibilities. Therefore, there are no anticipated costs associated with the implementation of this proposed rule language. One benefit associated with the language is the clarification to nursing homes of the responsibilities which can be expected of their medical director. Since there was direct involvement by medical directors in the development of this language, it contains reasonable expectations. Another benefit of the proposed language is the assurance to residents and nursing home staff that there is a physician involved in the development and implementation of resident care policies and procedures, a physician is available to serve as liaison with the residents' attending physicians, and participates on the Quality Assessment and Assurance (QAA) Committee.

PART 4658.0705 MEDICAL CARE AND TREATMENT

There are no costs associated with this part of the proposed rule language; the revisions to current rule language are generally just grammatical changes, often matching the federal certification language more closely. Benefits include the coordination of rules and regulations.

PART 4658.0710 ADMISSION ORDERS AND PHYSICIAN EVALUATIONS

There are no costs associated with this part of the proposed rule language. The revisions to current rule language are made generally to more closely match federal certification language, so the state rules would no longer conflict with the federal requirements. Benefits include the coordination of rules and regulations.

PART 4658.0715 MEDICAL INFORMATION FOR CLINICAL RECORD

There are no costs associated with this part of the proposed rule language; the revisions to current rule language are generally just grammatical changes, with the addition of two items which are suitable for this section of rules. These are items H and I, advanced directives, and physician contacts with the resident's family or representative. Benefits include the coordination of rules and regulations.

PART 4658.0720 PROVIDING DAILY ORAL CARE

Subpart 1: Although much of the proposed language is new to the state licensing rules, there are no anticipated costs associated with its implementation because it basically states what is expected as "dental services appropriate to [the residents'] needs", which is the current rule. The state Medicaid rules and manual were used for reference to ensure that the proposed language would correlate with what may be reimbursed under that program. The benefits of the proposed language include the assurance to residents that there are standards for daily oral care in nursing homes, and clarification to providers of what is appropriate daily oral care for residents. According to the residents, advocates, nursing home staff, and dental providers contributing suggestions for rule revisions, this is an area which has not been adequately addressed in the state rules and which needed specification and clarification.

Subpart 2: There are no anticipated costs associated with the implementation of the seven-day time frame for labeling dentures because many dentures are labeled at purchase, and most nursing homes have found it to be much more efficient and cost effective to label dentures right away upon admission. This is a customer service for residents, and the benefits include resident satisfaction, and a relative ease of locating lost or misplaced dentures so residents are more comfortable, can eat as they normally do, and do not suffer oral problems because they go without dentures for a period of time.

PART 4658.0725 PROVIDING ROUTINE AND EMERGENCY ORAL HEALTH SERVICES

The proposed revisions to this part more closely match the federal certification language than does the current rule, and also correlate with the State Plan for Medicaid reimbursement. Current nursing home staff can accomplish the referral or help make an appointment as a part of their regular duties so there are no anticipated costs associated with the implementation of this language. The benefits of these proposed revisions include a correlation with the federal certification and reimbursement language, and a strengthening of resident rights in regards to adequate routine and emergency oral health services.

PART 4658.0730 NURSING HOME REQUIREMENTS

Subpart 1: There are no anticipated costs associated with the implementation of this proposed language. Staff are required to be competent and trained in the cares they provide, under current federal and state regulations.

Subpart 2: There are no anticipated costs associated with the implementation of this subpart because dental care providers have indicated to the Department that the proposed language is the standard of practice, although parts may not be specifically included in current regulations. Dental providers and facility staff reported to the Department that by having better policies and

procedures and better trained staff to provide oral cares, it is likely that residents will enjoy better oral health which directly affects their overall health. The benefits of these proposed revisions, then, include improving resident health, comfort, treatment, and well-being. And with those improvements in resident health (or at least maintenance of resident health) the nursing home might be expected to have decreased costs of providing cares.

Subpart 3: Certified nursing facilities are already required to assist residents in making appointments and by arranging for transportation to and from the dentist's office.

Subpart 4: There should be no additional costs associated with the implementation of this subpart, since nursing homes are currently required to provide dental services appropriate to the needs of the residents. This subpart is merely clarification that residents who cannot travel out of the nursing home are to be provided with opportunities for dental care, if on-site services are available in the community. The benefit of this proposed language is the clarification of the resident right to cares and services to meet their needs.

Subpart 5: Although this is a revision to current language, there are no anticipated costs because the maintenance of a list of available dentists can be accomplished as a part of normal operation of the nursing home.

PART 4658.0750 PENALTIES FOR PHYSICIAN AND DENTAL SERVICES

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders. The benefits of having a rule part addressing penalty assessments include the assurance to consumers that there is an incentive to nursing homes to comply with the regulations, and the provision of a clear statement to nursing homes and to government regulators of the penalty for noncompliance with each rule part.

Infection Control

PART 4658.0800 INFECTION CONTROL

There are no anticipated costs associated with the implementation of this proposed part addressing the infection control program, the direction and elements of that program, and standards of practice. The proposed language is mainly an incorporation of federal requirements and an updating of current state language, while also incorporating national standards of practice as developed by the Association for Practitioners in Infection Control (APIC). One benefit of this proposed language is the consolidation of current state rules on infection control into one section, while including those other regulatory and professional standards, making it easier to find the rules dealing with infection control. Another benefit of the proposed language is the clarification and specification of what the minimum requirements are for an effective and reasonable infection control program, thus protecting the health, safety, comfort, treatment, and well-being of residents, family, visitors, volunteers, and staff. An effective infection control program developed specifically for a nursing home is very likely to actually save the nursing home money because infections will be prevented or controlled, saving facility resources for other expenditures rather than infection control and prevention.

PART 4658.0805 PERSONS PROVIDING SERVICES
There are no anticipated costs associated with this proposed language since it is an updating of current rule language, and also incorporates federal standards as set out in the Americans With Disabilities Act (ADA).

PART 4658.0810 RESIDENT TUBERCULOSIS PROGRAM
There are no anticipated costs associated with this proposed language since it is an updating of current rule language, and incorporates current standards of practice for the control of tuberculosis.

PART 4658.0815 EMPLOYEE TUBERCULOSIS PROGRAM
There are no anticipated costs associated with this proposed language since it is an updating of current rule language, and incorporates current standards of practice for the control of tuberculosis.

PART 4658.0820 FOOD POISONING AND DISEASE REPORTING
There are no anticipated costs associated with this proposed language since it is an updating of current rule language.

PART 4658.0850 PENALTIES FOR INFECTION CONTROL
There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders. The benefits of having a rule part addressing penalty assessments include the assurance to consumers that there is an incentive to nursing homes to comply with the regulations, and the provision of a clear statement to nursing homes and to government regulators of the penalty for noncompliance with each rule part.

Medication and Pharmacy Services

PART 4658.1300 DEFINITIONS
There are no costs associated with this proposed subpart since it contains definitions to clarify the terms used in other parts of these rules. The benefit of this proposed part is the clarification of terms used in these rules.

PART 4658.1305 PHARMACIST SERVICE CONSULTATION
The language being proposed in this part incorporates current federal certification language. Therefore, for the 99% of the licensed nursing homes in Minnesota which are also certified to participate in the federal Medicare and Medicaid programs, there will be no additional costs associated with implementing this proposed language. Six of the seven licensed only nursing homes who responded to a questionnaire already have pharmacy consultants so this should pose no new costs for these homes. The benefit of this proposed rule is that consultation from pharmacists will ultimately affect the health, safety, treatment, comfort, and well-being of the residents as well as provide a safety mechanism for both staff and residents by ensuring that a

system is developed to periodically reconcile controlled drugs.

PART 4658.1310 DRUG REGIMEN REVIEW

The language proposed in this part incorporates current federal certification language. Since 99% of the licensed nursing homes in Minnesota are certified to participate in the federal Medicare and Medicaid programs, there will be no additional costs to those facilities by implementing the proposed language. Six of seven licensed only nursing homes responded to a questionnaire from the Department. Five of these licensed only nursing homes already have a pharmacy consultant doing monthly drug reviews, so there should be no additional costs associated with implementing this proposed language. Part of the drug regimen review includes reporting irregularities to the director of nursing and, if appropriate, to the attending physician. The benefit of this proposed rule is for the resident. Noting irregularities and requiring that they be acted on is a health care issue for the residents.

Although proposed item C is new language in these proposed rules, it is an added benefit for residents because it ensures a backup system to provide an additional review of irregularities should the director of nursing or attending physician disagree with the pharmacist recommendations. Since certified nursing homes are currently required to have a Quality Assessment and Assurance Committee (QAA) [at 42 CFR 483.70(o)], and licensed only nursing homes are required to have a patient care policy committee at 4655.1400 (G), nursing homes in Minnesota are should already be in compliance with this proposed requirement. Therefore, there are no anticipated costs of implementing this part of the proposed rules because pharmaceutical issues would be a topic appropriately addressed by current committees.

4658.1315 UNNECESSARY DRUG USAGE

There are no anticipated costs of implementing this part since this proposed rule also incorporates language patterned after current federal certification language and again, 99% of licensed nursing homes in Minnesota are certified to participate in the Medicare and Medicaid programs. The benefits to requiring residents to be free of unnecessary drug usage would be that residents have additional monitoring to assure they receive care and services to attain or maintain their highest practicable physical, mental, and psychosocial well-being, without being subject to unnecessary drug use.

4658.1320 MEDICATION ERRORS

Although this proposed language is new, there are no anticipated costs associated with its implementation. All nursing homes already strive to be without medication errors. The 99% of licensed nursing homes that are certified to participate in the federal Medicare and Medicaid programs are already required to be free of medication error rates of 5% or greater. The benefits of this proposed rule would be that residents would have a greater chance to receive the correct medications which would directly affect their physical, mental and psycho-social well-being.

There are no anticipated costs of implementing item C since this proposed language is a revision and clarification of current state rule language. The benefits of changing this language are to provide clarification and strengthening of resident rights in the area of reporting significant

medication errors or resident reactions to the physician, the resident, or the resident's legal designee. Significant medication errors could directly impact the health, safety, comfort treatment, and well-being of residents.

4658.1325 ADMINISTRATION OF MEDICATIONS

The language being proposed in subpart 1 is patterned after current federal certification language. Therefore, for the 99% of the licensed nursing homes in Minnesota which are also certified to participate in the federal Medicare and Medicaid programs, there will be no additional costs associated with implementing this proposed language. As previously stated, six of the seven licensed only nursing homes who responded to a questionnaire already have pharmacy consultants so this should not pose new costs for these homes. The benefit of adding this language to state rules is to provide assurance that the pharmaceutical needs of each resident are met.

There are no anticipated costs of implementing subpart 2 since the proposed language is a revision of current state rule language. Nursing homes in Minnesota are already expected to have qualified staff responsible for medication administration. The benefit of this subpart is to ensure safe and proper medication administration to residents by trained staff.

There are no costs associated with the implementation of proposed subpart 3 since it contains current rule language with the deletion of an age requirement.

There are no costs associated with the implementation of proposed subparts 4, 5, and 6 since they update current rule language and incorporate more of the resident rights provisions in the state and federal regulations. The benefits of these proposed subparts are the clarification of medication administration requirements for self-administration, injections, and adding medications to foods. These clarifications enhance resident rights, quality of care, and quality of life.

There are no anticipated costs of implementing subparts 7 and 8 since the proposed language is a revision of current state rule language. Nursing homes in Minnesota are already required to be meeting the intent of these proposed subparts addressing administration requirements and documentation. The benefits of this requirement are the assurance to residents that medications are administered safely and properly recorded.

4658.1330 WRITTEN AUTHORIZATION FOR ADMINISTERING DRUGS

There are no anticipated costs for implementing this part since the proposed language is a revision of current state rule language. The benefits of this proposed requirement are the clarification of the requirements for who has the authority to prescribe medications.

4658.1335 DRUGS IN STOCK

There are no anticipated costs of implementing subpart 1 since the proposed language is a revision of current state rule language. The benefit of proposed language is to allow for the

identification of medication to the point of administration, thus allowing for safer distribution of medications.

There are no anticipated costs of implementing subpart 2 since the proposed language is a revision and updating of current state rule language. Benefits of updating the language include strengthening the coordination of federal and state regulatory language, including language from Board of Pharmacy Rules. Proposed language benefits residents by assuring that issues are identified that negatively affect the quality of care and services provided to residents. Another benefit is to ensure that emergency medications are available to meet resident needs, thus providing quality care for residents.

There are no costs associated with the proposed language of subpart 3 because it is a revision of current state rule language. The benefit of this language is the assurance that the resident will receive the medications prescribed and purchased for that resident.

4658.1340 MEDICINE CABINET AND PREPARATION AREA

There are no anticipated costs of implementing subpart 1 since the proposed language is a revision of current state rule language and incorporates federal certification language. Nursing homes in Minnesota should already be meeting the proposed requirements. The benefit of the proposed language would be to ensure that residents and unauthorized persons do not have access to others' medications. Another benefit would be that keeping medications under proper temperatures would ensure that the identity, strength and quality of the drug be maintained.

No costs are anticipated for implementing subpart 2 since the proposed language is a revision of current state rule language and also incorporates federal certification language. The benefit of the proposed language would be to decrease the risk of abuse of controlled drugs.

4658.1345 LABELING OF DRUGS

There are no anticipated costs of implementing this part since the proposed language is a revision of current state rule language while also incorporating federal certification language. Nursing homes in Minnesota are currently required to meet the intent of this proposed rule.

4658.1350 DISPOSITION OF MEDICATIONS

There are no anticipated costs associated with the implementation of this proposed subpart 1 since it contains current rule language. Nursing homes in Minnesota are already expected to be meeting the intent of this proposed rule part addressing the disposition of medications. The benefit of this proposed language to state rules is to save the nursing home time at the time of discharge or transfer by not having get a physician's order for the release of the resident's medications.

There are no anticipated costs associated with the implementation of this proposed subpart 1, item B, since it is a revision of current state rule language and therefore nursing homes in Minnesota are already expected to comply with this proposed rule. The benefit of adding

language to allow the consulting pharmacist to furnish the necessary instructions is to make this information more easily attainable by the nursing home.

There are no anticipated costs associated with the implementation of this proposed subpart 1, item C, since it is a revision of current state rule language. The benefit of changing "supervising nurse" to "nursing staff" is to give the nursing home more flexibility in determining who may be authorized or allowed to destroy medications. Another benefit of this language is to coordinate the language with Board of Pharmacy Rules.

There are no anticipated costs associated with the implementation of this proposed subpart 1, item D, since it is a revision of current state rule language. The benefit of revising this proposed rule is to clarify who is responsible for witnessing the destruction or disposition of unused drugs.

There are no anticipated costs associated with the implementation of this proposed subpart 2, since it is a revision of current state rule language. The benefit of this proposed language is to clarify which controlled drugs, namely Schedule II drugs, need to have a loss or spillage notation made.

There are no anticipated costs associated with the implementation of this proposed subpart 3, since it is a revision of current state rule language, and nursing homes in Minnesota are already expected to be meeting this requirement. The additional language added to this proposed rule benefits the nursing home by making it easier for nursing home staff to locate information relating to returning medications to the pharmacy.

4658.1355 MEDICATION REFERENCE BOOK

There are no anticipated costs associated with the implementation of this proposed part, since it is a revision of current state rule language and nursing homes in Minnesota are already to be expected to be meeting this requirement. The benefit of revising the language is that it allows the nursing home the flexibility to choose a medication reference that will meet the nursing home's and its residents' needs.

4658.1360 ADMINISTRATION OF MEDICATIONS BY UNLICENSED PERSONNEL

There are no anticipated costs associated with the implementation of this proposed subpart 1, since it is a revision of current state rule language and nursing homes in Minnesota are already expected to be meeting this requirement. The benefit of revising the proposed language is to allow nursing homes the flexibility of having their own medication administration course. The benefit of adding language delineating topics to be covered in this medication administration course is to provide clarification of the requirements to ensure safe and appropriate medication administration is being taught.

There are no costs associated with the implementation of proposed subpart 2 since it contains current rule language.

Although the proposed language in subpart 3 would be new to the rules, there are no anticipated costs associated with its implementation. The benefits to this added language are for clarification purposes.

4658.1365 PENALTIES FOR MEDICATIONS AND PHARMACY SERVICES

There are no anticipated costs of implementing this part since there are no mandatory duties imposed on the nursing home by the language. The statute requires a schedule of fines for non-compliance with correction orders. The benefits of having a rule part addressing penalty assessments include the assurance to consumers that there is an incentive to nursing homes to comply with the regulations, and the provision of a clear statement to nursing homes and to government regulators of the penalty for noncompliance with each rule part.

SMALL BUSINESS CONSIDERATIONS

Minnesota Statutes, §14.115, generally requires the Department to consider five methods for reducing the impact of the rule on small businesses. However, subdivision 7 exempts rules that affect "service business regulated by government bodies, for standards and costs, such as nursing homes, long-term care facilities, hospitals, providers of medical care, day care centers, group homes, and residential care facilities...." It is the Department's position that these rules regulating services provided in nursing homes is exempt from §14.115, because nursing homes are specifically exempted in that statute.

EXPERT WITNESSES

If a public hearing is held on this rule, the Department does not plan to solicit outside expert witnesses to testify on behalf of the Department. The Department intends to have the following employees testify or be available at the hearing: Mike Tripple, Maggie Friend, and Dena Dunkel. Other staff may testify or be available to answer questions about specific aspects of the proposed rule. Other staff may substitute for those named above.

Dated: 9/3/94

Mary Jo O'Brien, Commissioner
Minnesota Department of Health