

Minnesota Attorney General: Administrative Rules Proceedings

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STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

TO : GEORGE PETTERSEN
Commissioner
Department of Health

DATE: 10/30/80

Attn: JOHN A. BREVIU
SAAG

FROM : H. THEODORE GRINDAL HTG
Special Assistant
Attorney General

PHONE: 297-3471

SUBJECT: Rules as Approved In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes.

Enclosed herewith are the rules you have submitted for approval. These rules have been approved by this office and filed with the Secretary of State. Note that they have NOT been filed with the State Register; this must be done promptly by your agency.

Upon receipt and before transmittal to your agency, however, it is important that you recheck these rules as to:

1. Affixation of the stamps of the Attorney General and Secretary of State to the last page of the rules;

2. Coverage by these stamps of all rules submitted; and

3. Inclusion of all pages of the rules in the approved set.

Directly following the approved rules is a complete set of required documents and transcript which must be retained with the rules by you or your agency.

If you have any questions in this regard, please contact me.

HTG/bw
Encl.
cc: Duane Harves
Susan Robertson

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the Adoption of Rules Relating to the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Home and Boarding Care Home.

AMENDMENT TO THE COMMISSIONER'S FINDINGS OF FACT, CONCLUSIONS AND ORDER ADOPTING RULES

On October 7, 1980, an order adopting the above-entitled rules, with supporting findings of fact and conclusions was signed by the Commissioner of Health. Inadvertently, a conclusion regarding an amendment to 7 MCAR § 1.064 A.3.f. was omitted. That amendment was discussed in Commissioner's Findings #23 and 24 and the amendment was incorporated into the attached copy of the rules as adopted. In order to correct this defect the following conclusion is made by the Commissioner:

q. Amend 7 MCAR § 1.064 A.3.f. by deleting the first sentence of 7 MCAR § 1.064 A.3.f.(b). p. 28

Another omission was found in Conclusion #n. of the Commissioner's Report. That conclusion withdrew the proposed amendment to the provisions of 7 MCAR § 1.049 C.1. in accordance with the Hearing Examiner's finding that the Department failed to demonstrate the need for and reasonableness of that rule. That conclusion should also have indicated that the references to the withdrawn rule should have also been deleted from the provisions of the Schedule of Fines, 7 MCAR § 1.057 C.3.b. and from the Schedule of Allowable Time Periods for Correction, 7 MCAR § 1.058 A.4. Due to those deletions, those two rules would also have to be renumbered. To cure this defect, Conclusion n. of the Commissioner's Report is amended as follows:

n. Withdraw the proposed amendments to 7 MCAR § 1.049 C.1. Delete 7 MCAR § 1.057 C.3.b. and 7 MCAR § 1.058 A.4. and renumber those rules accordingly. OK OK p. 21 OK p. 23

These amendments shall be attached to and made part of the Commissioner's Findings of Fact, Conclusions and Order Adopting Rules, dated and signed on October 7, 1980.

Dated: October 9, 1980

George R. Pettersen, M.D.
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the Adoption of Rules Relating to the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Home and Boarding Care Homes

COMMISSIONER'S FINDINGS OF FACT, CONCLUSIONS AND ORDER ADOPTING RULES

The above-entitled matter came on for hearing before the Commissioner of Health at 9:30 a.m. on Tuesday, April 1, 1980, in Room 105 of the Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, after proper notice had been given as required by Minn. Stat. §§ 15.0411 to 15.0417 and 15.052. The hearing was concluded on April 2, 1980.

After giving interested persons an opportunity to present written and oral information, statements and arguments, having heard all of the testimony, having considered all the evidence adduced and upon the records, files and proceedings herein, and applicable statutory standards and criteria, and having confirmed the need for the above-captioned rules, the Commissioner hereby adopts as his own the Findings and Conclusions reported by the Hearing Examiner in his report dated May 20, 1980. (HLTH-80-040-GB) and also adds the following Findings of Fact and Conclusions in response to concerns raised by the Hearing Examiner in his Report.

A copy of the Hearing Examiner's Findings and Conclusions is attached hereto and made a part hereof.

The Commissioner makes the following additional:

Findings of Fact

Statement of Anticipated Costs and Benefits

1. In Finding of Fact #13, the Hearing Examiner found that the Statement of Anticipated Costs and Benefits, submitted pursuant to the provisions of Minn. Stat. § 144A.29, met the minimum requirements imposed by that statute. However, the Hearing Examiner also noted that this statement did not fully meet the spirit of the statute by failing to estimate the anticipated costs for those rules which do not impose mandatory requirements on a nursing home or boarding care home. I find that the Department did fully comply with the statutory mandate to the best of its ability.

2. A number of the rules presented at the public hearing provided options which a nursing home or boarding care home could elect to provide, e.g. handling of patients' and residents' funds, admitting or retaining individuals in need of oxygen on a nonemergency basis, and installing locks on patient bedroom doors in nursing homes. The enactment of those rules would not, per se, result in any additional costs to a nursing home or boarding care home. Costs would only be incurred when a decision would be made by facility personnel to offer a particular service. Since the Department is not in the position to either ascertain with any reasonable accuracy, the number of facilities that would elect to provide a service or to determine the extent that such services are already provided (which would offset any increased cost to the facility), the Department could not prepare a cost statement which would indicate the anticipated cost of a particular rule with any reasonable degree of accuracy. The Department believes that the facility, which is in the best position to assess the cost impact of a rule, must decide whether or not to provide an optional service. The development of a cost statement on an optional service by the Department would have been speculative and possibly misleading, if solely relied upon by a facility in deciding the cost impact of a particular rule.

Handling of Patients' and Residents' Personal Funds - 7 MCAR § 1.048 A.8.

3. In Finding of Fact #17, the Hearing Examiner referenced the testimony requesting that the proposed licensing rule be withdrawn until the release of the similar federal certification regulation. The final federal regulation, 42 CFR 405.1121(m) was printed in the Federal Register on July 24, 1980 and will become effective on October 22, 1980. The federal regulations have been compared with the proposed licensing rules and it is the Department's position that the federal and state provisions are generally compatible and will not present significant difficulties in either implementation or enforcement. However, as will be discussed below, the Department has amended a few sections of the rules to assure greater compatability with the federal requirements. While those amendments were not proposed during the period that the hearing record was open, the Department does not consider those changes to be substantial in nature.

4. In Finding of Fact #21, the Hearing Examiner suggested that the Department consider whether or not an amendment proposed after the hearing will adequately

ensure access by patients, residents and other designated persons to the personal account records. The original proposed rule, 7 MCAR § 1.048 A.8.c.(4)(a) required that a minimum access period of one hour five days per week be provided. In response to testimony presented at the hearing, the Department submitted a post-hearing amendment, found to be needed and reasonable by the Hearing Examiner, which would require that a nursing home or boarding care home to develop a policy specifying the time periods for access. The proposed amendment would require that the access periods be provided to meet the needs of patients and residents.

5. The Department still believes that the post-hearing amendment is appropriate. The Department believes that some flexibility should be provided to a facility in establishing the procedures for the handling of personal funds, particularly since this is a new rule. It should be noted that if difficulties arise in this area, the rule could be amended at a later date.

6. In Finding of Fact #22, the Hearing Examiner requested that the Department address the concerns raised by a number of witnesses regarding the handling of personal funds of individuals considered to be incompetent but not legally adjudicated as such. As pointed out by the Hearing Examiner, the concerns raised at the hearing, are not capable of an easy resolution. 7 MCAR § 1.048 A.8.b.1. requires that the authorization for a facility to handle the personal funds come from the "patient or resident or from the patient's or resident's legal guardian or conservator." A problem arises in situations when a patient or resident is believed to be "incompetent," and no guardian or conservator has been appointed. The rule would result in situations where the facility could not handle the funds even though this might be the most desirable result unless a guardian or conservator was appointed or by having an authorization signed by the patient or resident despite the voidable nature of such transaction.

7. In order to provide a solution to these concerns raised at the hearing, the Department has amended the authorization rule and the rules relating to access to financial records, 7 MCAR § 1.048 A.8.c.(4)(a); furnishing the quarterly statement, 7 MCAR § 1.048 A.8.c.(4)(b); the authorization to make withdrawals,

7 MCAR § 1.048 A.8.c.(4)(c)(ii); and access to funds, 7 MCAR § 1.048 A.8.c.(7); to include a "representative payee" as an individual having such authorities. The inclusion of the "representative payee" would also make the licensing rule consistent with the federal certification regulations.

8. The term "representative payee" would be defined in a new section, 7 MCAR § 1.048 A.8.b.(3) as "an individual designated by the Social Security Administration to receive benefits on behalf of the patient or resident."

9. The functions and responsibilities of the "representative payee" are defined in 20 CFR 404.1601 et seq., and 20 CFR 416.601, et seq., the Social Security Administration regulations governing the Old-Age, Survivors and Disability Insurance and the Supplemental Security Income programs, respectively. The two provisions are similar in nature.

10. The Social Security regulations require that the person seeking to be designated as the representative payee submit evidence "of his or her care and concern for, relationship to, or responsibility for the care of, the recipient or on whose behalf payment is to be made or of his or her authority to receive such payment....", 20 CFR 416.610. This requirement provides assurance that a representative payee would have some relationship or concern for the individual patient or resident. In addition, the Social Security regulations impose a fiduciary responsibility on the representative payee to properly use and account for the benefits received.

11. Since the appointment of a "representative payee" would not necessitate the cost and delay that may be associated with the appointment of a guardian or conservator and since the regulations of the Social Security Administration provide assurance as to the appropriate selection of an individual as well as impose duties to properly use and account for the use of funds, the amendment of the licensing rule to incorporate the term "representative payee" is needed and reasonable.

12. This amendment will also alleviate the majority of concerns expressed at the public hearing regarding the handling of funds of "incompetent persons". Friends or relatives of a patient or resident or nursing home or boarding care home

personnel would be able to request the appointment of a representative payee without resorting to the initiation of legal proceedings for the appointment of a guardian or conservator. It should also be noted that, under the federal regulations, all certified facilities will be required to take steps to assist those individuals incapable of managing their funds and for whom no representative has been appointed. (42 CFR 405.1121(m)(14)). One of those steps includes requesting the Social Security Administration to appoint a "representative payee." If a patient is not eligible for Social Security benefits, the facility, under the federal regulations, would be responsible for the initiation of proceedings to appoint a guardian or conservator.

13. While this amendment is made subsequent to the close of the hearing, the inclusion of the "representative payee" is not considered a substantial change. First, this amendment addresses concerns raised both, at the hearing and by the Hearing Examiner's Report. Second, the Department does not believe that this amendment would affect a class of persons not represented at the hearing, goes to a new subject matter of significant substantive effect, makes a major substantive change that was not raised by the original Notice of Hearing, or results in a rule fundamentally different from that contained in the Notice of Hearing. Moreover, consistent with testimony offered by nursing home representatives at the hearing, this amendment will ensure compatability with the new federal regulation on this subject.

14. In Finding of Fact #27, the Hearing Examiner requested that the Department consider amending the provisions of 7 MCAR § 1.048 A.8.c.(6) to require that facilities deposit funds in interest-bearing accounts to be consistent with the federal regulations and the testimony of resident groups that interest-bearing accounts are needed. The certification regulations, which impose mandatory requirements on all skilled nursing facilities and intermediate care facilities, require that interest-bearing accounts be utilized. Thus, since the federal regulations are more stringent, certified nursing homes and boarding care homes will be required to utilize interest-bearing accounts and to prorate interest in accordance with the federal requirements. (42 CFR 405.1121(m)(8)(ii) and (iii). However, the Department does not consider it appropriate to mandate, as part of the licensing rule, that interest-bearing

accounts be utilized. The Department's intent in developing the proposed rule was to provide adequate protection to the personal funds of patients and residents. Therefore, the Department felt that it was necessary to assure that any accrued interest be prorated to the individual patient; however, the Department felt that the mandatory use of interest-bearing accounts would not provide any additional protection to the funds of the patient or resident and should not be considered as a minimum standard.

15. In Finding of Fact #29, the Hearing Examiner indicated that the Department may wish to consider whether a number of days provided to return funds held outside of the facility should be changed. The rules presently require that these funds be returned within 3 banking days, 7 MCAR § 1.048 A.8.c.(7) and d. The federal regulation, 42 CFR 405.1121(m)(9)(ii), requires that funds held outside the facility be returned within 5 business days. To provide consistency with the federal requirement, the licensing rules are amended to provide 5 business days to return funds. This is not a substantial change in the requirements.

16. 7 MCAR § 1.048 A.8.c.(5) requires patient funds in excess of $100.00 to be deposited in a financial institution. The corresponding federal regulation, 42 CFR 405.1121(m)(8)(ii), requires that funds in excess of $150 be deposited in a financial institution. An amendment to the licensing rule will provide consistency with the federal regulation and would not be a substantial change. Allowing a facility to keep an additional $50.00 in a petty cash fund or similar arrangement would not adversely affect the rights of patients and residents.

17. 7 MCAR § 1.048 A.8.d. requires that the personal funds be returned at the time of a patient's or resident's discharge to "the patient or resident or to an authorized individual...." Since the rule does not specify who an "authorized individual" would be, clarification of that phrase is necessary. Other sections in this rule clearly delineate the responsibilities of other persons by specifically mentioning the guardian, conservator, or person designated in writing, by the patient or resident. Therefore, this section should be amended to be consistent with the other provisions in the rules and will read as follows:

> Upon discharge of a patient or resident, unless the patient's or resident's bed is being held for anticipated readmission, all funds of that patient or resident shall be returned to the patient or resident or the patient's or resident's legal guardian or conservator, representative payee or other person designated in writing by the patient or resident,....

The inclusion of the term "representative payee" is consistent with Finding #7 above, and is not a substantial change.

Use of oxygen - 7 MCAR § 1.046 L.

18. The review of the language of 7 MCAR § 1.046 L.2.f. necessitated a minor revision in order to clarify the meaning of that rule.

The rule currently reads:

> Written policies and procedures shall be developed and implemented regarding the care, storage, cleaning and sanitizing of oxygen tanks, equipment and supplies.

The literal requirements of that rule would necessitate that procedures be developed for the sanitizing of the oxygen tanks which would not be done by a nursing home. The supplies of the oxygen tanks and not the nursing home has the responsibility for purging and cleaning the tanks prior to refilling. Therefore, to eliminate any confusion over the interpretation of this section, the rule has been amended by deleting "tanks," from this section. This amendment is not a substantial change.

Tuberculosis Testing of Employees - 7 MCAR § 1.047 A.

19. In Finding of Fact #36, the Hearing Examiner requested that the Department consider a number of post-hearing comments regarding 7 MCAR § 1.047 A.1.b. That rule requires that an employee, having a positive tuberculin test, annually submit a report of a negative chest X-ray for five years after the positive tuberculosis test was documented. The post hearing comments generally requested that the five year period be reduced.

20. The Department believes that the five year period required by the rule must be retained since it is during this period that individuals are at the highest risk of developing the disease. The five year period is also reasonable when the population served by facility employees and the potential for exposing a large number of persons is considered. Individuals who

remain well after the first five years have a low risk of developing the disease and, once the five year period has elapsed, further testing is not required by the rule. It should also be noted that physicians would normally evaluate individuals with a positive reaction to ascertain whether these individuals should receive preventive therapy. If preventive therapy is successfully completed (which takes one year), further testing is not required. Thus, it would be possible for individuals having a positive reaction to avoid receiving X-rays for a five year period.

Chemical Sanitizing Dishwasher - 7 MCAR § 1.055 U.

21. In Finding of Fact #46, the Hearing Examiner requested that the Department consider a modification to the requirement that counter space for at least 4 racks of dishes and utensils be provided if a chemical sanitizing dishwasher is used, 7 MCAR § 1.055 U.1.b.(1)(c).

22. The Department believes that it is necessary to maintain this requirement to assure that space is provided to allow for the air drying of dishes and utensils, which is a particular concern due to the lower temperatures used in the chemical sanitizing dishwashers. However, the Department would be able to review specific situations where exact compliance could not be attained through the variance and waiver mechanism. This mechanism would allow alternative measures to be devised by a facility if the required counter space is not available.

Locks on Bedroom Doors - 7 MCAR § 1.064 A.3.f.

23. In Finding of Fact #49, the Hearing Examiner requested that the Department clarify that portion of the rule which states that locks on bedroom doors "can be locked only from the corridor side."

24. As was noted in the Statement of Need and Reasonableness, the existing prohibition against the use of locks on patient bedroom's in nursing homes was suspended by the Legislative Commission to Review Administrative Rules. The suspension was based on the concerns expressed by residents and others as to the need for security and privacy. The security issue is adequately addressed in the rule by providing a means to lock doors. However, the

ability to lock a door for privacy reasons is obscured by the requirement that doors "be locked only from the corridor side". The Department believes that the decision as to whether doors can be locked while residents are in the room must be made by the administration and residents of each facility. The rule specifically requires that the facility address this issue in its policy. Since safety concerns relate primarily to the ability to leave a room without the use of a key and to assuring that staff has access to master keys, the Department is deleting the first sentence of 7 MCAR § 1.064 A.3.f.(2) which contains the phrase requiring that doors be lockable from the corridor side only. That phrase is misleading and subject to misinterpretation. The deletion of the phrase is not a substantial change.

Variance and Waivers - 7 MCAR § 1.044 X.

25. In his Report, the Examiner identified three issues which the Department was to consider prior to the adoption of a final rule. Those issues were:

    1. Whether the Department should adopt an amendment providing that:
        a. The request for a variance or waiver would not be considered an admission of a rule violation;
        b. Fines would not accrue while a variance or waiver request is being processed; and
        c. That additional time for correction be provided in the event that a variance or waiver request is denied. (Finding of Fact #50)
    2. Whether alternative measures or conditions attached to a variance or waiver should continue to have the same fine amount and time period for correction as the rule for which the variance or waiver was granted. (Finding of Fact #54); and
    3. Whether the rules should establish a time limit for the Department's decision on a variance or waiver request. (Finding of Fact #57)

26. The Department does not believe that additional amendments to the variance and waiver rule are required. The Department's primary purpose for promulgating this rule was to provide a remedy to handle situations in which a facility finds it impossible to comply with the literal provision of the rule or when compliance would create an undue burden for the facility. The rule should not provide a method by which facilities could delay compliance

with correction orders by submitting requests for variances and waivers which would not fit the established criteria. The Department believes that the adoption of the proposed amendments would increase the possibility that the rule could be utilized to delay compliance and unduly interfere with the Department's ability to enforce the licensing rules. The Department considers the granting of a variance or waiver to be an extraordinary remedy to assist those facilities that have demonstrated, in a good faith manner, serious difficulties in attempting to comply with the licensing rules.

27. The proposed amendment which would provide that the submission of a request for a variance or waiver would not be construed as an admission of a rule violation fails to take into consideration that statutory provisions governing the issuance of correction orders and penalty assessments. Those provisions require that the Department conduct an inspection prior to the issuance of a correction order. The statutes also require that a reinspection be conducted prior to the issuance of a penalty assessment. Even if a facility requests a variance or waiver, as the result of the issuance of a correction order, a penalty assessment could not be issued until after a reinspection has been completed. This proposed amendment also creates an implication that the variance and waiver rules may be used to delay compliance with correction orders by allowing facilities to submit variance or waivers and be free from any liability or responsibility if those requests are frivolous, made in a bad-faith manner, or intended to provide additional time for correction. The Department did not promulgate the variance and waiver rule to penalize a facility; however, the Department believes that the use of a request for a variance or waiver to support a finding of non-compliance is an enforcement decision to be made by the Department based on the specific circumstances in each case and believes that a general rule, such as the one proposed, would be inappropriate and could possibly result in the submission of frivolous requests.

28. For similar reasons, the Department cannot support an amendment which would automatically provide additional time for correction if the request for a variance or waiver is denied. It should be noted that a request for a variance or waiver is not contingent upon the recipient of a correction order,

and thus, a rule providing for additional time for correction would not always be relevant. Even in situations where a correction order is outstanding, a mechanism is established in 7 MCAR § 1.058 B., to request additional time, if necessary. Since an existing mechanism is in place, the Department does not believe that an additional amendment to the variance and waiver rule is required. The granting of additional time for correction must be based on the circumstances surrounding each case. An automatic extension of time would provide an opportunity to use the variance and waiver rule as a means to delay compliance.

29. Concerning the proposed amendment that would prevent the accrual of fines during the review process, such an amendment would be clearly in contravention of the statutory provision, Minn. Stat. § 144A.10, subd. 6, regarding the daily accumulation of fines and, therefore, cannot be adopted.

30. 7 MCAR § 1.044 X.4. provides that any alternative measures or conditions attached to a variance or waiver will be subject to the issuance of correction orders and penalty assessments. The rule also provides that the fine amounts and period of times for correction specified for the rule for which a variance or waiver is sought would apply to the alternative measures or conditions. Post-hearing comments submitted to the Hearing Examiner indicated that it would not be reasonable to automatically apply the same fine level and time periods to alternative measures that might be different in nature and scope from the rule. Even though the Hearing Examiner found the rule to be reasonable; he asked the Department to consider a suggested amendment in this regards.

31. The Department does not believe that the proposed amendment would be possible or desirable. The issuance of a variance or waiver gives the facility permission to not comply with the minimum requirements specified in the rule. However, the granting of the variance or waiver is contingent upon the Department's determination that the residents of the facility would not be jeopardized by allowing a deviation from the rule. Since compliance with the provisions of the rules would not be required, it is necessary to provide some protection to the resident by establishing a means to assure that

the facility will be responsible for complying with any alternative measures or conditions. Since compliance with the licensing rules is attained through the use of the correction order/penalty assessment system, the proposed rule provides that the alternative measures will be subject to the issuance of correction orders.

32. The statutes governing the issuance of correction orders and penalty assessments require that a schedule of fines as well as a schedule of allowable time periods for correction, be promulgated by rule. Therefore, in order to issue correction orders and, if necessary, fines for non-compliance with an alternative measure or condition, rules must establish the schedule of fines and the schedule for allowable periods of time. Obviously, it would not be possible to establish time periods or fine levels for alternative measures which may be approved some time in the future. Accordingly, the Department felt that it was necessary and reasonable to utilize the time periods and schedule of fines established for the particular rule in order to assure that an effective method for compliance is maintained.

33. The schedule of fines and allowable periods of time for correction are based on the nature and scope of the particular rule and the Department believes that any alternative measures undertaken by a facility will be similar to the requirements imposed by the rule. Even if an alternative measure would be different from the rule, the Department does not believe that the adoption of the proposed amendment would be desirable. As stated above, it is important to provide an effective method for assuring compliance with the terms of a variance or waiver and the correction order/penalty assessment system provides that mechanism. Since the schedule of fines is based on the degree of harm that could result if a facility does not comply with a correction order, it is reasonable to assume that failure to conform to the alternative measures would create the same risk of harm to the residents of the facility. Accordingly, it is appropriate for an identical assessment to be issued for a violation. It should also be pointed out that, if necessary, the schedule of allowable time periods for correction provides for an extension of time.

34. Concerning the request that the rules contain a time limit for action on a

waiver request, the Department does not believe that such a requirement would add to the efficiency of the review process. Such a rule would not provide any sanction on the Department for failing to meet the deadline, and other than providing a benchmark to govern the processing time, such an amendment would serve no purpose. The Department realizes the concern that extended delays can cause, and will make certain that variance and waiver requests are handled as quickly and efficiently as possible, consistent with the necessity for a thorough review to fully protect patients and residents.

Schedule of Fines - 7 MCAR § 1.057

35. At the hearing, the Department added an additional subsection to 7 MCAR § 1.057 C.2. which was designated as subsection z. The correct numberical placement for this subsection should be subsection f. and this change has been made and the remaining subsections of section C.2. renumbered accordingly.

Allowable Time Periods for Correction - 7 MCAR § 1.058

36. In his Report, the Hearing Examiner suggested that the Department consider the following two issues:

    1. Whether the 24 hour time period to submit a written confirmation of a request should be changed to "one business day;" (Finding of Fact #67); and
    2. Whether the rule should provide for a contested case hearing in the event a request is denied. (Finding of Fact #8)

37. Under the provisions of 7 MCAR § 1.058 B.2.b., if the request is made orally, a written confirmation is to be mailed within 24 hours. A post hearing comment suggested that "24 hours" be changed to "one business day". The Department's rationale for the 24 hour period, as contained in the Statement of Need and Reasonableness, was as follows:

> ...the 24 hour time limit is necessary to assure that the information will be promptly submitted to the Department, so that the evaluation of the request can be accurately and quickly made,...The administrator at the time of the oral request will have the necessary information available and it would be not unreasonable to require that this information be put in writing and mailed to the Department within 24 hours after making the verbal request.
>
> Statement of Need and Reasonableness, pp 72-73.

However, the Department does not believe that a change to "one business day" would unduly delay the review process for considering extension requests and, therefore, this rule is amended to provide "one business day" for the mailing of the written confirmation. This is not a substantial change.

38. 7 MCAR § 1.058 B.5. provides that the nursing home will be notified, in writing, of a denial of an extension request and informed of the reasons for the denial. A suggestion was made to include an appeal mechanism to contest a denial of additional time by the Department. The Hearing Examiner found the rule as presently written, to be needed and reasonable. The Department does not believe that the inclusion of an appeal mechanism is necessary. The facility has advance notice of the criteria that will be used to evaluate the request and will be informed of the reasons for any denial. The inclusion of an appeal mechanism will significantly delay the period of time for compliance. Under the contested case provisions of the Minnesota Administrative Procedures Act, a delay of at least 2 to 3 months would result any time an appeal is sought. The Department believes that such a mechanism could be abused and may result in the submission of inappropriate hearing requests for the purpose of gaining additional time for compliance.

Based upon the foregoing Findings of Fact, the Commissioner makes the following:

CONCLUSIONS

1. That the rules be amended in accordance with the Hearing Examiner's Report, dated May 20, 1980 and in accordance with the foregoing Findings of Fact as follows:
   a. Amend 7 MCAR § 1.044 X.2.e. to read: "Such other relevant information necessary to properly evaluate the request for the variance or waiver." (Hearing Examiner's Report, Finding #52 and Conclusion #3).
   b. Amend the last sentence of 7 MCAR § 1.044 X.7. to read: "At the hearing, the applicant shall have the burden of proving that it satisfied the criteria specified in section 3., above, except in a proceeding challenging the revocation of a variance or waiver." (Hearing Examiner's Report, Finding #58 and Conclusion #3).

c. Amend the first sentence of 7 MCAR § 1.046 L. to read:

> "Oxygen may be used in a nursing home on an emergency or nonemergency basis."
> (Hearing Examiner's Report, Finding #32)

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d. Amend 7 MCAR § 1.046 L.2.f. to read:

> "Written policies and procedures shall be developed and implemented regarding the care, storage, cleaning and sanitizing of oxygen equipment and supplies."
> (Commissioner's Finding #18)

p. 5.

e. Delete the last sentence of 7 MCAR § 1.047 A. which reads:

> "The nursing home and boarding care home shall reimburse their employees for the costs, if any, of obtaining the necessary tests which demonstrate freedom from tuberculosis."

p. 6

f. Amend 7 MCAR § 1.048 A.8.b. by adding the following subsection:

(3) A "representative payee" is an individual designated by the Social Security Administration to receive benefits on behalf of the patient or resident.

(Commissioner's Finding #8)

p. 9.

g. Amend 7 MCAR § 1.048 A.8.b.(1) as follows: The personal funds of the patient or resident shall not be accepted for safekeeping without written authorization from the patient or resident or from the patient's or resident's legal guardian or conservator, or representative payee.
(Commissioner's Finding #7)

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h. Amend 7 MCAR § 1.048 A.8.c.(4)(a) as follows: "Each patient or resident and the patient's or resident's legal guardian or conservator, representative payee, or other person..." (Commissioner's Finding #7)

p. 10

i. Amend 7 MCAR § 1.048 A.8.c.(4)(b) as follows: "Each patient or resident or the patient's or resident's legal guardian or conservator, representative payee or other person..." (Commissioner's Finding #7)

p. 10

j. Amend 7 MCAR § 1.048 A.8.c.(4)(c)(ii), as amended at the hearing as follows:

> "The name of all individuals, other than the patient or resident, who have been authorized, in writing by the patient or the resident or the patient's or resident's guardian or conservator or representative payee, to withdraw or expend funds from the patient's or resident's personal account." (Commissioner's Finding #7)

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k. Amend 7 MCAR § 1.048 A.8.c.(5), as amended by the Department after the hearing as follows:

> "Unless otherwise specified by law, the personal funds of any patient or resident in excess of $150.00..." (Commissioner's Finding #16)

p. 11

l. Amend 7 MCAR § 1.048 A.8.c.(7), as follows:

> "Upon the request of the patient or resident or the patient's or resident's legal guardian or conservator or representative payee.... Funds kept outside of the facility shall be returned within five business days". (Commissioner's Findings #7 and 15)

p. 11

m. Amend 7 MCAR § 1.048 A.8.d. as follows:

> "...all funds of that patient or resident shall be returned to the patient or resident or to the patient's or resident's legal guardian or conservator, representative payee, or other person designated in writing by the patient or resident, with a written accounting,....Funds which are maintained outside of the nursing home shall be returned within five business days." (Commissioner's Findings #15 and 17)

p. 12

n. Withdraw the proposed amendments to 7 MCAR § 1.049 C.1. (Hearing Examiner's Report, Finding #38 and Conclusion #4)

withdrawn

o. Renumber the subsections of 7 MCAR § 1.057 C.2. (Commissioner's Finding #35)

p. Amend 7 MCAR § 1.058 B.2.b. as follows:

> "If the request for an extension is made orally, the administrator shall mail, within one business day, a written confirmation which contains the information specified under section 2.a., above." (Commissioner's Finding #37)

2. That the Commissioner has demonstrated the need for and reasonableness of the amendments to the nursing home and boarding care home rules.

Based upon the foregoing Findings of Fact and Conclusions, the Commissioner issues the following:

ORDER

IT IS HEREBY ORDERED:

That the attached rules relating to the construction, equipment, maintenance, operation and licensing of nursing homes and boarding care homes, identified as 7 MCAR § 1.044 X; 7 MCAR § 1.046 L.; 7 MCAR § 1.047 A.; 7 MCAR § 1.048 A.4.; 7 MCAR § 1.048 A.8.; 7 MCAR § 1.052 A.1.; 7 MCAR § 1.053 F,; 7 MCAR § 1.055 U.;

7 MCAR § 1.057; 7 MCAR § 1.058; and 7 MCAR § 1.064 A.3.f. are adopted this 7th day of October, 1980, pursuant to the authority vested in me by law.

Dated: October 7 , 1980

George R. Pettersen, M.D.
Commissioner of Health

ADMIN 1000 (Rev. 1/78)
SF-00006-01

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

TO : Ted Grindal
Special Assistant
Attorney General

DATE: October 30, 1980

FROM : John A. Breviu
Special Assistant
Attorney General

PHONE: 341-7272

SUBJECT: Nursing Home Rule Amendments

You are authorized to correct the following typographical errors in the Nursing Home Rule Amendments:

1. Page 4: Rule .046L.1. - first line - Comma after oxygen should be deleted.

2. Page 5: Rule .046L.2.d. - first line - Same correction as above.

3. Page 17: Rule .055U.1.b(2)(d) - Insert "machine" before "manufacturer."

JAB:sil

AG. copy.

7 MCAR § 1.044 Definitions, general provisions, issuance of licenses.

X. Variance and waivers.

1. General provisions. A nursing home or boarding care home may request that the Department grant a variance or waiver from the provisions of these rules.

2. Contents of request. All requests for a variance or waiver shall be submitted to the Department in writing. Each request shall contain the following information:

   a. The specific rule or rules for which the variance or waiver is requested;

   b. The reasons for the request;

   c. The alternative measures that will be taken if a variance or waiver is granted;

   d. The length of time for which the variance or waiver is requested;

   e. Such other relevant information necessary to properly evaluate the request for the variance or waiver.

HE 52
FofF 1a.

3. Criteria for evaluation.

   a. The decision to grant or deny a variance or waiver shall be based on the Department's evaluation of the following criteria:

      1. The variance or waiver will not adversely affect the health, treatment, comfort, safety or well-being of a patient or resident;

HE 53

      2. The alternative measures to be taken, if any, are equivalent to or superior to those prescribed in the rules; and

      3. Compliance with the rule or rules would impose an undue burden upon the applicant.

   b. The applicant shall be notified in writing of the Department's decision. If a variance or waiver is granted, the notification shall specify the period of time for which the variance or waiver will be effective and the alternative measures or conditions, if any, to be met by the applicant.

4. Effect of alternative measures or conditions. All alternative measures or conditions attached to a variance or waiver shall have the force and effect of the licensure rule(s) and shall be subject to the issuance of correction orders and penalty assessments in accordance with the provisions of Minn. Stat. 144.653 and 144A.10. The period of time for correction and the amount of fines specified for the particular rule for which the variance or waiver was requested, shall apply.

5. Renewal.

   a. Any request for the renewal of a variance or waiver shall be submitted in writing prior to its expiration date. Renewal requests shall contain the information specified in section 2. above.

   b. A variance or waiver shall be renewed by the Department if the applicant continues to satisfy the criteria contained in section 3. above and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance or waiver was granted.

6. Denial, revocation or refusal to renew. The Department shall deny, revoke or refuse to renew a variance or waiver if it is determined that the criteria specified in section 3. above are not met. The applicant shall be notified in writing of the decision to deny, revoke or refuse to renew the variance or waiver, informed of the reasons for the denial, revocation or refusal to renew, and informed of the right to appeal this decision. HE 57

7. Appeal procedure. An applicant may contest the denial, revocation or refusal to renew a variance or waiver by requesting a contested case hearing under the provisions of the Administrative Procedures Act, Minnesota Statutes § 15.0411 et. seq. The applicant shall submit, within 15 days of the receipt of the Department's decision, a written request for a hearing. The request for hearing shall set forth in

detail the reasons why the applicant contends the decision of the Department should be reversed or modified. At the hearing, the applicant shall have the burden of proving that it satisfied the criteria specified in section 3. above, except in a proceeding challenging the revocation of a variance or waiver.

HE 58
FOF 16

7 MCAR § 1.046 General Policies

L. Use of oxygen.

HE 32 F9 F1c

1. Oxygen, may be used in a nursing home on an emergency or nonemergency basis. A registered nurse or other person trained in the use of oxygen shall be responsible for its administration and shall be on duty during the entire time that oxygen is administered. The following precautions shall be taken:

   a. Signs indicating "No Smoking" shall be placed at the bedside and at the entrance to the room.

   b. All matches, ash trays and other smoking material shall be removed and kept out of the room.

   c. No oil or grease shall be used on oxygen equipment.

   d. Oxygen tanks shall be securely anchored when stored or in use.

2. A nursing home, which admits or retains patients in need of oxygen, on other than an emergency basis, shall comply with the following provisions:

   a. The nursing home shall provide 24 hour licensed nurse coverage, unless it only admits patients who can self-administer oxygen.

   b. The patient's attending physician shall submit written orders for oxygen, and, if self-administration of oxygen is also ordered, the physician shall specify that the patient is mentally and physically capable of administering oxygen without the assistance of the nursing home staff.

   c. The Patient Care Policy Committee shall develop and implement written policies regarding the provision of oxygen in the nursing home. These policies shall at a minimum, include:

      (1) Any limitations placed on the patient or other patients such as room assignments and smoking policies.

      (2) Any restrictions placed on patients using portable oxygen equipment as to mobility within the facility or participation in activities.

(3) A mechanism to periodically assess those patients authorized to self-administer oxygen as to their continued capability to self-administer it.

(4) Precautions to be taken, in addition to those in section 1.a.-d., above, to assure the safe use of oxygen.

d. All nursing homes which admit patients in need of oxygen, shall inform these patients of any limitations or restrictions imposed by the nursing home prior to admission or at the time the use of oxygen is ordered by the physician.

e. The director of nursing shall be responsible for providing training to the nursing home staff regarding the procedures to be followed for the administration of oxygen, for monitoring the use and effectiveness of oxygen, special precautions to be taken, and the care and cleaning of equipment.

f. Written policies and procedures shall be developed and implemented regarding the care, storage, cleaning and sanitizing of oxygen equipment and supplies.

3. All oxygen used in the nursing home shall be from cylinders which bear labelling indicating that the oxygen is for medical purposes.

7 MCAR § 1.047 Personnel.

A. Tuberculosis testing of employees. The nursing home or boarding care home shall be responsible for assuring that all employees, prior to employment and as otherwise indicated in this rule, show freedom from tuberculosis in accordance with the provisions of this section. FofFle deletion. HE 34

1. All employees, unless certified in writing by a physician to have had a positive reaction to a standard intradermal tuberculin test, shall have a standard intradermal tuberculin test with purified protein derivative (Mantoux) within 45 days prior to employment.

   a. If the tuberculin test is negative, the employee shall be considered free from tuberculosis.

   b. If the tuberculin test is positive or if the employee's physician has certified a positive reaction to the tuberculin test, the employee shall submit prior to employment and annually thereafter, a written report by a physician of a negative full-sized chest X-ray taken within the previous 45 days. Annual written reports of the employee's negative chest X-ray shall be required for five years after a documented positive standard intradermal tuberculin test, after which time the employee shall be considered free from tuberculosis.

2. All employees showing positive reaction to the tuberculin test who have taken a complete course of preventive therapy as directed by their physician, shall be considered free from tuberculosis at the completion of the program and shall be exempt from the testing requirements of this section.

3. Written documentation of compliance with the above requirements shall be filed in the employee's personnel record.

7 MCAR § 1.048 Records and reports.

(APPLIES TO BOTH NURSING HOMES AND BOARDING CARE HOMES)

A. Patient or Resident Care Record. An individual chart shall be kept on each patient and resident admitted to the home. All entries shall be made with a pen and signed by the person making the entry. Accurate, complete and legible records for each patient or resident from the time of admission to the time of discharge or death shall be kept current and shall be maintained in a chart holder at the nurses' or attendants' station.[1]

1. Admission Record. The admission record shall be initiated for each patient and resident within 72 hours after admission and contain identifying information including: name, previous address, social security number, sex, marital status, age, date and place of birth, previous occupation, date and hour of admission; name, address and telephone number of the nearest relative, and the person to be notified in an emergency or death; information as to funeral arrangements, if available; church affiliation and pastor; and the name of the patient's or resident's attending physician. At the time of discharge or death, this record shall be completed with the date, time, reason for discharge, discharge diagnosis and condition; or date, time and cause of death. In either case the signature and address of the responsible person to whom released shall be obtained.

2. Medical Record. The medical record shall be initiated for each patient or resident within 72 hours in accordance with MHD 49 (c).

3. Filing and Disposition of Records. The patient or resident care record shall be incorporated into an individual folder and filed at the nurses' or attendants' station.[1] The records of discharged patients or residents shall be promptly completed and filed in the home.

Patients' or residents' medical records and patient care plans in nursing homes shall be considered confidential but they shall be made

[1] A central control point for the storage of records and medications.

7 MCAR § 1.048 A. continued

available to all persons in the home who are responsible for the care of the patient or resident and they shall be open to inspection by representatives of the Department. When a patient or resident is discharged to another care facility pertinent information relative to his care shall accompany the patient or resident.

4. Storage and Preservation of Records. Space shall be provided for the safe storage of patients' or residents' records at the nurses' or attendants' station[1] and in general storage. Records shall be filed so as to be readily accessible. All patients' and residents' records shall be preserved for a period of at least 5 years following discharge or death.

5. Census Register. A register shall be kept in a separate bound book, listing in chronological order the names and dates of all admissions and discharges. This register shall be kept in such a manner that total admissions, discharges, deaths and patient or resident days can be calculated.

6. Reports to the Department. Reports regarding statistical data and services furnished shall be submitted on forms furnished by the Department. Copies shall be retained by the home.

7. Correspondence with Department. All correspondence with the Department shall be kept as a permanent, accessible record.

8. Record of Patients' and Residents' Funds.

HE 19

a. Admission Policy. The admission policies of the nursing home and boarding care home shall specify whether the home will accept the personal funds of patients' or residents' for safekeeping. If the nursing home or boarding care home accepts the personal funds of patients' and residents' for safekeeping, written policies

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[1] A central control point for the storage of records and medications.

7 MCAR § 1.048 A., continued

regarding the handling and protection of the funds shall be established in accordance with this section.

b. Authorization.

(1) The personal funds of the patient or resident shall not be accepted for safekeeping without written authorization from the patient or resident or from the patient's or resident's legal guardian or conservator or representative payee.

(2) A copy of this written authorization shall be retained in the patient's or resident's records.

(3) A "representative payee" is an individual designated by the Social Security Administration to receive benefits on behalf of the patient or resident.

c. Personal Fund Accounts

(1) The personal funds of patients' and residents' shall not be commingled with the funds of the nursing home or boarding care home or with the funds of any person other than patients or residents of the home, unless otherwise authorized by law.

(2) The personal funds of patients' and residents' shall not be used in any way for the purpose of the nursing home, boarding care home or any other patient or resident and shall be free from any liability that the nursing home or boarding care home incurs.

(3) A person, firm, partnership, association or corporation which operates more than one facility licensed in accordance with the provisions of Minnesota Statutes § 144.50-.56 or Minnesota Statutes, Chapter 144A shall not commingle patient or resident funds from one facility with another.

7 MCAR § 1.048 A., continued

(4) A written accounting system for the personal funds of patients and residents shall be developed and maintained.

(a) Each patient or resident and the patient's or resident's legal guardian, or conservator, representative payee or other person designated by the patient or resident shall be allowed access to the written records of all financial arrangements and transactions involving the individual patient's or resident's funds in accordance with the nursing home's and boarding care home's written policy. Such policy shall assure that access be provided in accordance with the needs of patients and residents.

(b) Each patient or resident or the patient's or resident's legal guardian or conservator, representative payee or other person designated in writing by the patient or resident, shall be given a written quarterly accounting of the financial transactions made by or on behalf of the patient or resident.

(c) An individual written record shall be maintained for each patient or resident which shall include the following items:

(i) The date, amount and source of funds deposited by or on behalf of a patient or resident.

(ii) The name of all individuals, other than the patient or resident who have been authorized in writing by the patient or resident or the patient's or resident's legal guardian or conservator or representative payee to withdraw or expend funds from the patient's or resident's personal account.

7 MCAR § 1.048 A., continued

(iii) The date and the amount of all withdrawals from the patient's or resident's personal account.

(5) Unless otherwise specified by law, the personal funds of any patient or resident in excess of $150.00 shall be deposited in a demand account in a financial institution authorized to do business in Minnesota, the deposits which are are federally insured, except that a facility that is operated by a county shall deposit such funds with the county treasurer. This account must be in a form which clearly indicates that the facility has only a fiduciary interest in the funds. Records shall be maintained which specify on whose behalf funds are deposited or withdrawn from this account. HE 26 FoF 1k.

(6) If a patient's or resident's personal funds are deposited in an interest bearing account, the accrued interest shall, unless otherwise specified by law, be prorated in accordance with the amounts attributable to each patient or resident and recorded on the patient's or resident's account.

(7) Upon the request of the patient or resident or the patient's or resident's legal guardian or conservator or representative payee, the nursing home or boarding care home shall return all or any part of the patient's or resident's funds given to the nursing home or boarding care home for safekeeping, including interest, if any, accrued from deposits. The nursing home or boarding care home shall develop a policy specifying the period of time during which funds can be withdrawn on each day of the week. Funds kept outside of the facility shall be returned within five business days. HE 18 FoF 1.2. HE. 28 FoF 1.2 HE29.

7 MCAR § 1.048 A., continued

d. Discharge of Patient or Resident. Upon discharge of a patient or resident, unless the patient's or resident's bed is being held for anticipated readmission, all funds of that patient or resident shall be returned to the patient or resident or to the patient's or resident's legal guardian or conservator, representative payee or other person designated, in writing, by the patient or resident with a written accounting in exchange for a signed receipt. Funds which are maintained outside of the nursing home or boarding care home shall be returned within five business days.

e. Death of a Patient or Resident. Upon the death of a patient or resident, the nursing home or boarding care home shall provide a complete accounting of that patient's or resident's funds.

9. Policy Records. All policies and procedures adopted by the home shall be placed on file and be made readily accessible to the personnel.

10. Unusual Occurrences. Any occurrence of food poisoning or reportable disease shall be reported immediately to the Department.

11. Employees' Personnel Records. A current personnel record shall be maintained for each employee and placed on file in a locked cabinet in the office of the administrator, person in charge or the business office. These records shall be available to representatives of the Department and shall contain the following information:

7 MCAR § 1.048 A., continued

a. Person's name, address, telephone number, age and birth date, sex, marital status, Minnesota license or registration number, if applicable; name, address and telephone number of person to be called in case of emergency; social security number, and similar identifying data.

b. Resume of individual's training, experience and previous employment; recommendations and references from previous employers.

c. Dates and results of any pre-employment physical examination and of any subsequent physical examinations.[1]

d. Date of employment in home, type of position currently held in home; hours of work, attendance and salary records.

e. The record of all illnesses and accidents.

f. A listing of all institutes or training courses attended.

g. At least annual evaluations concerning employee's work performance.

h. Date of resignation or discharge and reason for leaving.

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[1] Annual physical examinations are recommended.

7 MCAR § 1.052 A.1. Patient and resident units

a. A comfortable bed at least 36 inches wide, good springs and a clean, firm comfortable mattress and mattress pad. At least one clean, comfortable pillow with extra pillows available to meet the patient's needs. Clean, light weight blankets and bed linen in good condition and of the proper size shall be kept on hand for use at all times. Clean sheets and pillow cases shall be furnished at least once a week. Each bed shall have a washable bedspread. A moisture-proof mattress cover or rubber or plastic sheeting shall be provided for mattresses of all bed patients and for other beds as necessary. Rollaway type beds, cots, or folding beds shall not be used.

b. The nursing home and boarding care home shall develop a written policy regarding the use of double beds.

7 MCAR § 1.053 Medications

F. Disposition of medications.

1. If authorized by the attending physician or the physician in charge, medications belonging to patients shall be given to them when discharged or transferred. This shall be recorded on the patient's chart. Unused portions of controlled substances shall be handled by contacting the Minnesota Board of Pharmacy who shall furnish the necessary instructions and forms, a copy of which shall be kept on file in the home for two years. Any other unused portions of prescription drugs remaining in the nursing home after the death or discharge of the patient for whom they were prescribed or any prescriptions discontinued permanently, shall be destroyed by the supervising nurse in the nursing home, by flushing them into the sewer system and removing and destroying the labels from the containers or handled in accordance with section F.2., below. A notation of any such destruction giving date, quantity, name of medication and prescription number shall be recorded on the patient's chart. Such destruction shall be witnessed and the notation signed by both persons.

2. Drugs and precribed medications, other than controlled substances, used in nursing homes may be returned to the dispensing pharmacy in accordance with the provisions of the Minnesota Board of Pharmacy rule, 7 MCAR § 8.032 B.

7 MCAR § 1.055 Dietary service and sanitation.

U. Dishwashing. The dishwashing operation shall provide proper separation in the handling of soiled and clean dishes and utensils, and shall conform with either HE 42 of the following procedures for washing, rinsing, sanitizing and drying.

1. Machine washing of dishes and utensils.

a. Hot water sanitizing. The dishwashing machine shall be operated in accordance with the manufacturer's instructions which shall be posted nearby; see MHD 67 (clii). The flow pressure shall be maintained between 15 and 25 pounds per square inch (psi) at the dishwasher. The temperatures of the water shall be maintained at 140°-160°F. for the washing cycle, and at 170°F. for the rinsing and sanitizing cycle, both temperatures measured at tray level. If the same person handles both soiled and clean dishes, he shall wash his hands between operations. Dishes and utensils shall be air dried.

b. Chemical Sanitizing.

(1) Equipment

(a) Dishwashing machines using chemicals for sanitizing shall bear the seal indicating that the machine meets the standards of the National Sanitation Foundation. HE 43

(b) Each dishwashing machine shall be equipped with a visual or audible signaling device which indicates when the chemical sanitizing supply is empty. The signaling device shall be maintained in an operating condition.

(c) The clean dish counter shall provide space for at least 4 racks of clean and sanitized dishes and utensils.

(2) Operation

(a) The dishwashing machines shall be operated in accordance

with the manufacturer's instructions which shall be posted nearby.

(b) The temperature of the wash water shall not be less than 140° F. (60° C.).

(c) Chemicals added for sanitation purposes shall be automatically dispensed in accordance with the manufacturer's specifications for time and concentration.

(d) The chemical sanitizing rinse water temperature shall not be less than 75°F. (24°C.) nor less than the temperature specified by the manufacturer as indicated on the NSF data plate.

(e) All chemical sanitizers used in the dishwashing machines shall bear labeling indicating that the chemical sanitizers are registered by the Environmental Protection Agency and shall contain specific instructions for use.

(f) A test kit or other device that accurately measures the parts per million concentration of the sanitizing solution shall be available and used in accordance with this section.

(i) The concentration level shall be tested in accordance with the manufacturer's instruction each day the machine is used. HE 48

(ii) The results of the testing shall be recorded in a written log which specifies the result of the test and shall be signed by the individual making the test. The log shall include the name of the chemical used and the manufacturer's recommended concentration of the chemical. This written log shall be maintained for the previous 3 months.

(g) If the same person handles both soiled and clean dishes, he shall wash his hands between operations.

(h) Dishes and utensils shall be air dried.

(i) The dishwashing machine shall be thoroughly cleaned at least once a day in accordance with the manufacturer's recommendation.

2. Hand Washing of Pots and Pans. A three-compartment scullery sink, see MHD 65 (b2aa3), shall be utilized as follows for a complete washing cycle by hand of pots and pans. The first compartment is for soaking and washing, the second compartment is for rinsing, and the third compartment for sanitizing. Sanitizing is accomplished by complete immersion for at least two (2) minutes in 170°F. water. A unit heater capable of maintaining the water in the sanitizing compartment at 170°F. shall be provided, including a long handled wire basket for the removal of the sanitized items. The temperature shall be monitored with a thermometer. If the mechanical dishwasher is used for sanitizing of pots and pans, a sanitizing compartment is not required. Only air drying is permitted.

7 MCAR § 1.057 Schedule of fines for uncorrected deficiencies.

(APPLIES TO BOTH NURSING HOMES AND BOARDING CARE HOMES)

A. A $50.00 penalty assessment will be issued under the provisions of Minnesota Statutes § 144.653, subd. 6 (1974) for non-compliance with correction orders relating to the sections of these regulations listed below.

MHD 44 (o); (p); (q); (s); (t); (u)

MHD 45 (a)(3); (f); (h)(1); (h)(2)(aa); (h)(2)(ff); (h)(4)

MHD 46 (a); (b); (j); (k)

MHD 47 (c); (e)

MHD 48 (a)(4); (a)(5); (a)(6); (a)(7); (a)(9); (a)(11)

MHD 50 (a); (j)

MHD 52 (a)(2); (a)(3); (a)(4); (a)(9); (d); (e)

MHD 54 (a)(7); (b)(5)

MHD 55 (i)

MHD 56 (f); (h)

MHD 64 (a)(22); (b)(15)

B. A $250 penalty assessment will be issued under the provisions of Minn. Stat. § 144.653, subd. 6 (1974) for non-compliance with correction orders relating to all other sections of these regulations not specifically enumerated in section A. or C.

C. Nursing Homes

1. A $50 penalty assessment will be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.048 A.4.

b. 7 MCAR § 1.048 A.8.a.

c. 7 MCAR § 1.048 A.8.b.(2)

d. 7 MCAR § 1.048 A.8.c.(3)

e. 7 MCAR § 1.048 A.8.c.(5)

f. 7 MCAR § 1.048 A.8.c.(6)

g. 7 MCAR § 1.048 A.8.d.

h. 7 MCAR § 1.048 A.8.e.

i. 7 MCAR § 1.052 A.1.b.

j. 7 MCAR § 1.053 F.2.

k. 7 MCAR § 1.055 U.1.b.(1)(c)

l. 7 MCAR § 1.064 A.3.f.(1)(a)

2. A $150 penalty assessment will be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.046 L.2.b.

b. 7 MCAR § 1.046 L.2.c.

c. 7 MCAR § 1.046 L.2.d.

d. 7 MCAR § 1.046 L.2.e.

e. 7 MCAR § 1.046 L.2.f.

f. 7 MCAR § 1.046 L.3. HE.59

g. 7 MCAR § 1.047 A.

h. 7 MCAR § 1.048 A.8.b.(1)

i. 7 MCAR § 1.048 A.8.c.(1)

j. 7 MCAR § 1.048 A.8.c.(2)

k. 7 MCAR § 1.048 A.8.c.(4)(a)

l. 7 MCAR § 1.048 A.8.c.(4)(b)

m. 7 MCAR § 1.048 A.8.c.(4)(c)

n. 7 MCAR § 1.048 A.8.c.(7)

o. 7 MCAR § 1.055 U.1.b.(1)(a)

p. 7 MCAR § 1.055 U.1.b.(1)(b)

q. 7 MCAR § 1.055 U.1.b.(2)(a)

r. 7 MCAR § 1.055 U.1.b.(2)(b)

s. 7 MCAR § 1.055 U.1.b.(2)(c)

t. 7 MCAR § 1.055 U.1.b.(2)(d)

u. 7 MCAR § 1.055 U.1.b.(2)(e)

v. 7 MCAR § 1.055 U.1.b.(2)(f)

w. 7 MCAR § 1.055 U.1.b.(2)(g)

x. 7 MCAR § 1.055 U.1.b.(2)(h)

y. 7 MCAR § 1.055 U.1.b.(2)(i)

3. A $250 penalty assessment shall be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.046 L.2.a.

b. 7 MCAR § 1.064 A.3.f.(1)(b)

7 MCAR § 1.058 Allowable time periods for correction.

A. Allowable time periods for correction. The allowable time periods for complying with a correction order issued by the Department shall be as follows:

1. 7 MCAR § 1.046	
a. L.2.a.	30 days
b. L.2.b.	14 days
c. L.2.c.	14 days
d. L.2.d.	14 days
e. L.2.e.	14 days
f. L.2.f.	14 days
g. L.3.	30 days HE 62
2. 7 MCAR § 1.047 A	14 days
3. 7 MCAR § 1.048	
a. A.4.	14 days
b. A.8.a.	30 days
c. A.8.b.	14 days
d. A.8.c.(1)	30 days
e. A.8.c.(2)	30 days
f. A.8.c.(3)	30 days
g. A.8.c.(4)(a)	14 days
h. A.8.c.(4)(b)	30 days
i. A.8.c.(4)(c)	30 days
j. A.8.c.(5)	30 days
k. A.8.c.(6)	30 days
l. A.8.c.(7)	14 days
m. A.8.d.	14 days
n. A.8.e.	14 days

4. 7 MCAR § 1.052 A.1.b.	30 days
5. 7 MCAR § 1.053 F.2.	30 days
6. 7 MCAR § 1.055	
a. U.1.b.(1)(a)	60 days
b. U.1.b.(1)(b)	30 days
c. U.1.b.(1)(c)	60 days
d. U.1.b.(2)(a)	14 days
e. U.1.b.(2)(b)	14 days
f. U.1.b.(2)(c)	14 days
g. U.1.b.(2)(d)	14 days
h. U.1.b.(2)(e)	14 days
i. U.1.b.(2)(f)	14 days
j. U.1.b.(2)(g)	14 days
k. U.1.b.(2)(h)	14 days
l. U.1.b.(2)(i)	14 days
7. 7 MCAR § 1.064	
a. A.3.f.(1)(a)	30 days
b. A.3.f.(1)(b)	14 days

B. Extension of the allowable time period for correction.

1. Request for extension. The nursing home may request an extension of the allowable time for correction for those rules specified in section A., above. The request for extension of the allowable period of time for correction shall be received by the Department prior to the expiration of the time period cited in the correction order. The failure to submit a request within that time period shall result in a denial of the request.

HE 65.

2. Contents of request.

a. All requests for an extension of the allowable time period for correction shall contain the following information:

(1) The identification of the rule or rules for which the correction order was issued;

(2) The date the correction order was received;

(3) The allowable time period for correction;

(4) The reasons for requesting an extension of the allowable time period for correction which shall specify, in detail, the steps that have been taken by the nursing home to attain compliance;

(5) The length of additional time required to attain compliance with the correction order; and

(6) Such other relevant information necessary to evaluate the request for the extension of time. HE 52

b. If the request for an extension is made orally, the administrator shall mail, within one business day, a written confirmation which contains the information specified under section 2.a., above.

3. Criteria for evaluation.

a. A request for an extension of the allowable period of time shall be granted if the Department determines that:

(1) Continued non-compliance with the rule for the length of the extension will not jeopardize the health, treatment, comfort, safety or well-being of the patient; and

(2) The nursing home:

(a) Has entered into a contract to obtain the materials, labor, personnel, or other items necessary to obtain compliance with the correction order, but the supplier, contractor or individual has failed to perform or is unable to perform within the time period specified and the inability of the nursing home to

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comply with the correction order is due solely to that failure; or

(b) Has otherwise made a diligent good faith effort to comply with the correction order since its receipt.

b. The administrator shall be notified, in writing, of the Department's decision. If an extension of time is granted, the notification shall specify the additional time allowed for correction.

4. Renewal.

a. Any request for the renewal of an extension of the allowable time period for correction shall be made in accordance with section B.1. and 2., above.

b. Approval for the renewal of an extension of the allowable time period for correction shall be granted if the Department determines that the nursing home continues to meet the criteria contained in section B.3., above.

5. Denial. The Department shall deny any request for an extension of the allowable time period for correction if it determines that the criteria specified in section B.3., above, are not met. The denial shall be in writing and shall list the reasons for the denial.

7 MCAR § 1.064 A.3,f. Bedroom Doors

(1) Existing and new.

(a) The nursing home shall develop a written policy regarding the use of locks on patient bedroom doors. The policy shall address whether or not doors can be locked while the patient is in the room.

(b) All such locks shall permit exit from the room by a simple operation without the use of a key. All locks shall be openable with a master key which is located at each nursing station.

Amended Eff F.

APPROVED AS TO FORM AND LEGALITY

OCT 29 19 80

WARREN SPANNAUS, ATTORNEY GENERAL

BY H. Theodore Tunheim

SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
OCT 30 1980

Secretary of State

3:45 P.M.

HLTH-80-040-GB

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes.

REPORT OF THE HEARING EXAMINER

The above-entitled matter came on for hearing before State Hearing Examiner George A. Beck at 9:30 a.m. on Tuesday, April 1, 1980, in Room 105 of the Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota. The hearing was concluded on April 2, 1980.

This Report is a part of a rule hearing procedure pursuant to Minn. Stat. §§ 15.0411 to 15.0417 and 15.052 to determine whether the proposed rules and rule amendments should be adopted by the Department of Health. A copy of this Report may be obtained from the Office of Hearing Examiners for the cost of reproduction.

Members of the agency panel appearing at the hearing included: Mike Tripple, Assistant Section Chief, Survey and Compliance Section, Minnesota Department of Health; Nancy Younger, Management Analyst, Survey and Compliance Section, Minnesota Department of Health; and John A. Breviu, Special Assistant Attorney General, representing the Minnesota Department of Health.

Sixty-nine persons signed the hearing register. Fifteen public witnesses appeared and spoke at the hearing. The Department submitted 17 written exhibits. Thirty-three timely written comments were received from the public prior to the close of the record.

Pursuant to Minn. Stat. § 15.0412, subd. 4 (1978), this Report shall be available for review to all affected individuals upon request for at least five days. Thereafter, the Department of Health shall, if it proposes to adopt the rules as originally proposed or amended, submit a copy of the Order Adopting Rules, a copy of any additional agency findings, a copy of the rules as originally proposed, and a copy of the rules as adopted to the Chief Hearing Examiner for review pursuant to Minn. Stat. § 15.052, subd. 4 (1978). The submission to the Chief Hearing Examiner shall precede review by the Attorney General. The Chief Hearing Examiner shall complete his review and submit his report to the Department on the issues of substantial changes in the rule and compliance with Minn. Stat. § 15.0412 (1978) within ten calendar days. The Department will be responsible for filing the rules with the Attorney General and for notifying persons who have indicated that they wish to be notified of such filing.

Based upon all the testimony, exhibits and written comments, the Hearing Examiner makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On February 26, 1980, the Department of Health filed the following documents with the Chief Hearing Examiner:

(a) A copy of the proposed rule amendments.
(b) The Order for Hearing.
(c) The Notice of Hearing proposed to be issued.
(d) A statement of number of persons expected to attend and length of hearing.

2. On February 25, 1980, the Notice of Hearing and the amendments as proposed were published at 4 State Register 317.

3. On February 26, 1980, the Notice of Hearing was mailed by the Department to all persons and associations who had registered their names with the Secretary of State to receive such notice, as well as to a supplementary list of nursing homes and boarding care homes and to a list of persons and associations known by the Department to be interested in departmental regulation and to all the members of the Minnesota Legislature.

4. On March 6, 1980, the Department filed the following documents with the Hearing Examiner:

(a) The Affidavit of Receipt of the Secretary of State's list.
(b) The Certificate of the Secretary of State.
(c) The Affidavit of Mailing of the Notice of Hearing.
(d) A Notice of Intent to obtain information published in the State Register on November 8, 1976, and materials received following the Notice.
(e) A Petition from Non-Agency Source requesting a rules hearing.
(f) The Statement of Need and Reasonableness.

The documents listed above were available for inspection at the Office of Hearing Examiners from the date of filing to the date of the hearing.

5. The record remained open through April 21, 1980, for the receipt of written comments and statements.

Statutory Authority

6. The Department of Health has cited three statutes as authority for the promulgation of the rule amendments; namely, Minn. Stat. §§ 144.56, 144A.08 and 144A.10 (1978). Minn. Stat. § 144.56 reads, in part, as follows:

> 144.56 STANDARDS. Subdivision 1. The state commissioner of health shall, in the manner prescribed by law, adopt and enforce reasonable rules, regulations, and standards under sections 144.50 to 144.56 which he finds to be necessary and in the public interests and may rescind or modify them from time to time as may be in the public interest, insofar as such action is not in conflict with any provision thereof.
>
> Subd. 2. In the public interest the commissioner of health, by such rules, regulations, and standards, may regulate and establish minimum standards as to the construction, equipment, maintenance, and operation of the institutions insofar as they relate to sanitation and safety of the buildings and to the health, treatment, comfort, safety, and well-being of the persons accommodated for care. Construction as used in this subdivision means the erection of new buildings or the alterations of or additions to existing buildings commenced after the passage of this act.

Minn. Stat. § 144A.08, subd. 1 provides as follows:

> 144A.08 PHYSICAL STANDARDS; PENALTY. Subdivision 1. Establishment. The commissioner of health by rule shall establish minimum standards for the construction, maintenance, equipping and operation of nursing homes. The rules shall to the extent possible assure the health, treatment, comfort, safety and well being of nursing home residents.

Minn. Stat. § 144A.10, subd. 4 provides as follows:

> Subd. 4. Correction orders. Whenever a duly authorized representative of the commissioner of health finds upon inspection of a nursing home, that the facility or a controlling person or an employee of the facility is not in compliance with sections 144A.01 to 144A.17 or the rules promulgated thereunder, a correction order shall be issued to the facility. The correction order shall state the deficiency, cite the specific rule or statute violated, state the suggested method of correction, and specify the time allowed for correction. The commissioner of health by rule shall establish a schedule of allowable time periods for correction of nursing home deficiencies.

Minn. Stat. § 144A.10, subd. 6 provides as follows:

> Subd. 6. Fines. 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 promulgated by rule of the commissioner of health. 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 $250 per day of noncompliance.

LCRAR

7. Most of the rule amendments proposed in the rule proceeding are based upon recommendations made by the Legislative Commission to Review Administrative Rules. (Ex. 10, Attachment A) On January 29, 1980, the LCRAR voted to request the Department of Health to hold a public hearing within 60 days of receipt of the request by the Department. The request was received by the Department of Health on February 5, 1980.

Compliance with § 15.0412, subd. 7

8. Minn. Stat. § 15.0412, subd. 7 provides as follows:

> Subd. 7. If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, the notice of the proposed rule as required by this section shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies in the state to implement the rule for the two years immediately following adoption of the rule if the estimated total cost exceeds $100,000 in either of the two years. For purposes of this section, local public bodies shall mean officers and governing bodies of the political subdivisions of the state and other officers and bodies of less than state wide jurisdiction which have the authority to levy taxes.

The Department did not include a written estimate with its Notice of Hearing as called for in this section. Both the Minnesota Association of Health Care Facilities (MAHCF) (Ex. FF, p. 3) and the law firm of Broeker, Hartfeldt, Hedges & Grant ("the Broeker firm") (Ex. GG, p. 3) believe that the costs of implementing the proposed amendments will exceed the statutory threshold. The MAHCF stated that since Minnesota counties pay approximately 4.43% of all

medical assistance costs, should these proposed rule amendments cause a statewide increase in expenditures of $2,256,336, then the $100,000 threshold in the statute would be exceeded. (This estimate does not appear to consider that only two-thirds of nursing home costs statewide are paid by medical assistance.) Additional costs created by the proposed amendments were cited as chest x-rays for residents upon admission and costs of tuberculosis testing for employees.

9. The Department replied that prior to issuing the Notice of Hearing, it had reviewed the subject matter of the proposed rules and determined that they would not require any expenditures by local bodies in excess of $100,000. (Ex. 17, p. 17) The Department estimates that the cost of tuberculosis screening for employees required by the rule amendments will cost somewhere between approximately $12,000 to $26,000 for the 90 publicly run facilities in the state. Presumably a similar cost would exist for the 360 some private homes reduced to the 4.43% figure for purposes of estimating the cost to local public bodies. Assuming that approximately two-thirds of the patients in nursing homes in Minnesota are medical assistance recipients, and assuming that counties contribute less than 5% of medical assistance costs, it would appear that the maximum cost increase for x-rays that the counties would have to bear would be in the neighborhood of $5,000. The Department believes that, as is explained further in its Statement of Anticipated Costs and Benefits, the remaining rules provide options to facilities and, thus, do not require expenditures by local public bodies until that option is exercised. (Ex. 17, p. 17) The record would not appear to support the contention that the proposed rule amendments would cause total costs in excess of $100,000 per year for local public bodies.

Statement of Anticipated Costs and Benefits

10. Minn. Stat. § 144A.29, subd. 4 states as follows:

> Each rule promulgated by the commissioner of health pursuant to section 144A.01 to 144A.17 shall contain a short statement of the anticipated costs and benefits to be derived from the provisions of the rule.

The Department did prepare a seven-page document pursuant to this statute. The Department estimated increased cost for only one rule; namely, the amendment to Section 1.047 A. in regard to tuberculosis testing of employees. In regard to several of the rules, the Department stated that it was not in the position to provide an indication of anticipated costs since the rules provided an option to the facility, such as the rules relating to handling of funds and the amendment proposed governing the administration of oxygen.

11. The MAHCF stated that the rules in regard to variances, the schedule of fines, and the allowable periods for correction will have costs to nursing homes and suggested that merely because it would be difficult for the Department to estimate costs, it does not mean that the Department need not make any attempt to do so. It also suggested that in fact since most facilities do handle patient funds, there will be increased costs as a result of the proposed rule amendment in that regard. (Ex. FF, pp. 2-3) The Broeker firm believes that the statement is deficient in that the Department has considered

only the costs which nursing homes will incur as a result of the rule amendments where it should have considered also the cost impact on the Department of Health itself, upon the resident, and upon the medical assistance program. (Ex. GG, p. 2; Tr. pp. 63-66) The Broeker firm also objected to the Department's failure to discuss the cost impact of the daily tagging system with its reinspection cost. The Broeker firm stated that the question of whether or not greater fines provide a greater deterrent should have been balanced in the statement, and that a discussion of the costs to the Department to enforce this new system should have been discussed. (Tr. pp. 222-230; Ex. GG, p. 29) The Broeker firm also criticized the Department's estimation in regard to the patient funds rule. They stated that in reality most nursing homes will handle patient funds and all will if the federal regulations as expected compel them to do so. Therefore, the Department should have attempted to estimate costs rather than simply stating that the rule was not mandatory. (Tr. pp. 99-100; Ex. GG, pp. 10-11) The Broeker firm also commented that no estimate of anticipated costs was made for the waiver rule or the requst for extension rule which they believe will show costs for staff time of the Department, as well as the provider. (Ex. GG, p. 24, 32; Tr. pp. 178-180)

12. The Department replied that it can reasonably be inferred that since the statute uses the phrase "short statement" an elaborate analysis is not required. The Department stated that the statute only requires an analysis of the costs the nursing homes will incur since the costs associated with the Department's enforcement is subject to detailed legislative scrutiny through the budget process. The Department reiterated that where the rules are not mandatory, it is not possible to anticipate costs since the number of facilities exercising the option is not known and cannot be estimated. (Ex. 17, p. 18)

13. The Department is correct in pointing out that the legislature did not intend a detailed statement of anticipated costs. It is clear, however, that it was intended that the Department should weigh costs against benefits in the process of rule promulgation. This goal is frustrated when the Department's effort stops at simply stating that a rule is not mandatory and, therefore, costs cannot be estimated. The spirit of the statute should require the Department to estimate what costs it believes will actually result. This would include an estimate as to how many facilities will comply or take advantage of the proposed rule. The record in this matter suggests that whether or not the federal regulations are promulgated, a large number of facilities would choose to handle patient funds under this proposed rule, and the Department could have made an estimate of the cost to the nursing home. The Department's interpretation of the statute as speaking only to costs to be incurred by facilities is reasonable. The Department has, nonetheless, met the minimum requirements of Section 144A.29, subd. 4, which does not impose a very heavy burden upon the Department.

Fiscal Note

14. The Department is also required by Minn. Stat. § 15.065 (1979 Supp.)

to file with the House Appropriations and the Senate Finance Committees a fiscal note if any rule has a fiscal impact in excess of $100,000 per year. (Ex. GG, p. 5; Ex. FF, p. 4) The statute requires that this be done before the rule is "put into effect". This statute is not limited to the effect upon local public bodies. The Department has stated that it will reevaluate the cost of the proposed rules and file the fiscal note, if required. (Ex. 17, p. 18)

Statement of Need and Reasonableness

15. Both the MAHCF and the Broeker firm made general criticisms of the Statement of Need and Reasonableness. The MAHCF stated that the Statement lacked specificity and did not contain facts but only general conclusions. (Ex. FF, pp. 1-2) The Broeker firm stated that the Statement was inadequate because it generally concludes that reasonableness is present without looking at the specific facts, alternatives or other relevant considerations. (Ex. GG, pp. 1-2) Although the adequacy of the Statement in regard to particular rules will be discussed later in this Report, it can be noted that a rule may, where apropriate, be supported by argument and reasoning as well as facts. Chapter 15 does not specifically require an agency to discuss possible alternatives, but only to support its own proposal.

Proposed Amendment to 7 MCAR § 1.048 A.8. - Record of Patients' and Residents' Funds

16. This proposed amendment sets up a specific procedure for the handling of resident funds by nursing and boarding care homes. It was suggested before the LCRAR that funds had been handled without proper authorization, commingling of funds had occurred, and that there was a lack of safeguards. The Minnesota Board on Aging spoke in support of the proposed rule amendments, citing three major recent fraud investigations regarding patient funds in Minnesota. The Board believes that a standard set of procedures will help to cure the problem. (Ex. M, pp. 1-3)

17. Both the MAHCF (Tr. p. 85; Ex. FF, p. 4) and the Broeker firm (Tr. p. 98; Ex. GG, p. 10) urged that this proposed rule amendment be withdrawn at this time and promulgated after the promulgation of a similar federal regulation so that consistency can be obtained. According to the record, there would be at least one difference, with the federal regulations having a different, although not necessarily inconsistent, requirement in regard to placing funds with financial institutions. The Department stated that it hoped to achieve consistency with future federal regulation, but believed that it should proceed with the proposed rule amendment at this time since it has the responsibility to provide for the well being of nursing home residents. The Department stated that it will review the federal regulation when it is finalized and should some inconsistency appear, propose an amendment to the state rule in question at a rulemaking hearing later this year. (Ex. 17, p. 3) The Broeker firm suggested, as it has in regard to a number of rules, that this rule is more than a "minimum standard", which they suggest is called for by the statute enabling the rules. (Tr. p. 98) The sense of the statute,

however, would seem to be that the Department is directed to set certain threshold standards which nursing and boarding care homes must meet, but not to preclude a detailed statement of what is required. The Broeker firm also raised the serious question of how an incompetent nursing home resident who is without relatives is to be treated under this rule without violating the proposed rule. They believe that this is a common situation which the rule does not address. (Ex. GG, p. 14)

18. The Minnesota Association of Homes for the Aging (MAHA) suggested, for the sake of consistency, that the term "legal guardian" be used wherever "guardian" appears in the rule in order to make the proposed amendment consistent. (Ex. J, p. 3) The Department agreed to this suggestion. (Ex. 17, p. 3)

19. Proposed amendment 1.048 A.8.a. requires the facilities' admission policies to specify whether or not the home will accept personal funds of residents for safekeeping. The Broeker firm suggested that the title of this subsection should be amended to read "Admission Policy". (Tr. p. 100; Ex. GG, p. 14) The Department agreed that this change should be made. (Ex. 17, pp. 3-4) The Board on Aging (Ex. M, p. 3), Friends and Relatives of Nursing Home Residents (FRNHR) (Ex. O, p. 1), the Nursing Home Residents Advocates (NHRA) (Tr. p. 82), and the Nursing Home Residents Advisory Council (NHRAC) (Ex. EE, p. 1), all stated that the proposed amendment should require nursing homes to handle patient funds when requested to do so rather than leaving the decision up to the facility. They stated that a bank or other financial institution is often inaccessible for a resident and that they are, therefore, effectively denied access to their funds if the nursing home declines to handle personal funds of residents. The MAHCF testified that the safekeeping of patient funds should be voluntary, and suggested that a mandatory rule would be beyond the statutory authority of the agency. (Tr. p. 86; Ex. FF, p. 4) In its written comments, the Department correctly states that an amendment of this rule subsection to make the handling of patient funds mandatory would be a substantial change which the Department would have to make in a subsequent rulemaking proceeding. The Department stated that they will consider the comments made for a possible later change in the rules. (Ex. 17, p. 4) The subsection is needed and reasonable as proposed.

20. Subsection 1.048 A.8.c.(3) prohibits the commingling of patient funds from one facility with those of another, even though the facilities might be owned by one corporation. The Department stated that this would provide a clear identity of funds from each nursing home for accounting purposes and provide for accessibility to these funds. The Board on Aging supported the proposed amendment, and stated that residents of one facility should not suffer if a related facility has financial difficulties. (Ex. AA, p. 1) The MAHA suggested deletion of this proposed amendment. (Ex. J, p. 3) The Broeker firm stated that the Department's presentation in support of this rule was inadequate since it was mostly conclusory and did not provide specific facts. (Ex. GG, pp. 11, 14) The Department stated that the subsection is intended to ensure that the personal funds of patients in one facility can be clearly identified from those funds of residents in another facility. (Ex.

17, p. 4) The amendment is needed and reasonable as proposed. Facts showing the reasonableness of a proposed rule need not necessarily be adjudicative, trial-type facts, but can also be legislative facts or argument in support of policy. St. Paul Area Chamber of Commerce v. Minnesota Public Service Commission, 251 N.W.2d 350, 356-7 (Minn. 1977); Davis, Administrative Law of the Seventies, Sec. 6.01-2 (Cumulative Supp. 1977, p. 65).

21. Section 1.048 A.8.c.(4)(a) provides for access to all written records in regard to personal funds and by implication, restricts access to the resident, the resident's legal representative or a person designated by the resident. The rule, as proposed, requires a minimum access of one hour five days per week. The Board on Aging (Ex. M, p. 4), FRNHR (Ex. O, p. 2), NHRA (Tr. p. 83), and the NHRAC (Ex. EE, p. 1), stated that access should be allowed at any time during the facility's normal business hours. The MAHCF stated that access should be left to each facility with no minimum stated since access could be disruptive to a facility's normal operations. (Tr. p. 87; Ex. FF, p. 5) The Department stated that it believes that the facility is in the best position to establish reasonable times for access and and concluded that it would propose deleting the last sentence of the subsection as originally proposed and substituting the following: "Such policy shall assure that access be provided in accordance with the needs of the patients and residents." The Department states that this language would require that the facility carefully consider the needs of residents and establish periods of access in accordance with those needs. (Ex. 17, p. 4) It is concluded that this subsection, as proposed to be amended by the Department, has been shown to be needed and reasonable. It is suggested, however, that the Department consider as a matter of policy whether or not its amendment proposed subsequent to the hearing will ensure adequate access in light of the concern expressed by the groups representing residents.

22. A further matter was raised by the Careview Home (Ex. U, p. 1) and the administrator of the Retirement Center of Wright County (Tr. pp. 95-97), and was also mentioned earlier by the Broeker firm. They stated that it is a common situation that a resident is not competent to designate a person to have access to his funds. The resident may also lack a legal representative. What commonly happens is that a family member is allowed access to the funds. However, the commentors are concerned that under the rule, as proposed, this would not be possible and might result in a correction order for a facility. The appointment of a legal guardian or conservator merely for the purpose of allowing access to patient funds is certainly not reasonable for most people. Although this problem is not one which is capable of an easy solution, it is one that should be addressed by the Department.

23. Section 1.048 A.8.c.(4)(b) requires that a written quarterly accounting of patient fund transfers be provided. The FRNHR supported the subsection, while the NHRAC and the Board on Aging urged that the rule specify that the statement be itemized so as to indicate individual deposits and withdrawals. (Ex. O, p. 2; Ex. M, p. 5; Ex. EE, p. 1) St. Benedict's Center suggested that since a quarterly accounting would be time-consuming, it should be provided only upon request. (Ex. K, p. 1) The NHRAC also suggested that the

word "given" be substituted for the word "provided" to ensure that the statement is received by the proper person. (Ex. EE, p. 1) The Department agreed to this suggestion. (Ex. 17, p. 5) The Department stated, however, that a specific designation as to the contents of the quarterly statement is not necessary, and believes that facilities should be able to provide information on the statements appropriate to the needs of the residents. Since the rule also limits access to the patient fund account as a safeguard, the Department believes that an itemized statement should not be mandated. (Ex, 17, p. 5) The rule, as proposed, is needed and reasonable.

24. At the hearing, the Department offered an amendment to Section 1.048 A.8.c.(4)(c)(ii) as originally proposed which would make the proposed language more specific and would result in a rule which reads as follows:

> The name of all individuals, other than the patient or resident, who have been authorized, in writing by the patient or the resident or the patient's or resident's guardian or conservator, to withdraw or expend funds from the patient's or resident's personal account. (Ex. 13, p. 1; Ex. 17, p. 1)

As amended, the proposed rule subsection is needed and reasonable.

25. Section 1.048 A.8.c.(4)(c)(iii) requires that the written records in regard to patient funds specify the date and amount of all withdrawals and, as originally proposed, requires a receipt for purchases made with patient funds. St. Benedict's Center (Ex. K, p. 1) and the Careview Home (Ex. U, p. 1) noted that requesting a receipt from a family member, for example, causes resentment and does not necessarily prevent abuse. The MAHCF and the Broeker firm (Tr. p. 87; Ex. FF, p. 5; Ex. GG, p. 12) noted that the facility cannot compel receipts to be provided, and suggested that House File 729, which was passed by the 1980 Legislature and which makes misuse of funds theft, is a sufficient deterrent to abuse. The Broeker firm stated that the Statement of Need does not support the receipt requirement. In its post-hearing comments, the Department proposed that the last sentence of this subsection be deleted. The Department believes that the other safeguards provided in the rule and the requirements of Minn. Stat. § 256B.35, as amended, provide sufficient control over the unauthorized use of funds. With the deletion, the proposed subsection is needed and reasonable.

26. Section 1.048 A.8.c.(5) requires patient funds in excess of $100 to be deposited in a trust demand account in an insured financial institution. The Department stated that the rule is necessary to assure the safety of patient funds. (Ex. 10, p. 29) Several comments (Ex. O, p. 1; Tr. p. 83; Ex. EE, p. 1) prefer that the funds be required to be in an interest-bearing account at least where the amount was over $150. The Department of Veterans Affairs (Ex. S) stated that Minn. Stat. § 198.265 requires them to deposits residents' funds with the State Board of Investment. In response to this last concern, the Department suggested that the first sentence be amended to read as follows:

> Unless otherwise specified by law, the personal funds of any patient or resident in excess of $100 shall be deposited in a demand account in a financial institution authorized to do business in Minnesota, the deposits of which are federally insured. (Ex. 17, p. 5)

The Broeker firm stated that this subsection is a major change, and that the Department's presentation is insufficient to constitute an affirmative presentation of facts. (Ex. GG, pp. 12, 14) Although the Department's presentation is minimal, the advantage to the resident of having his funds in excess of $100 in a checking account as opposed to being kept at the facility is apparent. The rule subsection, as amended by the Department's post-hearing comments, is needed and reasonable.

27. Section 1.048 A.8.c.(6) permits a facility to deposit personal funds in an interest-bearing account, and then requires that the interest be pro rated to each patient. The Board on Aging and the NHRAC (Ex. M, p. 4; Ex. EE, p. 1) again supported requiring interest-bearing accounts since residents have little money and since the proposed federal regulation would require it. The MAHCF commented that it is very difficult to pro rate interest, and that this requirement should be amended since it will discourage use of interest-bearing accounts. (Tr. pp. 89-90; Ex. FF, p. 5) The Broeker firm urged that the word "attributable" should be further defined to specify a time period or date. (Ex. GG, p. 14) The Department stated that mandating the use of interest-bearing accounts would not provide any additional safeguard which is the purpose for the proposed rule. (Ex. 17, p. 6) The rule is needed and reasonable as proposed; however, the agency should consider the possibility of consistency with the federal regulation and the testimony of residents groups that interest-bearing accounts are needed.

28. Section 1.048 A.8.c.(7) requires the facility to return the patient's funds upon request during time periods set by the facility and requires funds kept outside of the facility to be returned within three banking days. At the hearing, the Department proposed that this rule subsection be clarified by rewording the second sentence so that it would read as follows:

> The nursing home or boarding care home shall develop a policy specifying the period of time during which funds can be withdrawn on each day of the week. (Ex. 13, p. 1)

Three commentors suggested that access for withdrawals should be during normal business hours, or should at least have a minimum number of hours. (Ex. M, p. 5; Tr. p. 83; Ex. EE, p. 1) The Department believes that the facility is in the best position to develop a policy responsive to the needs of residents in this instance. (Ex. 17, p. 2, 6) The Broeker firm indicated that it believes that the justification for the three banking days' provision is inadequate. (Ex. GG, p. 12) The rule subsection is needed and reasonable as amended.

29. Section 1.048 A.8.d. provides that when a patient is discharged, personal funds shall be returned to him, and where the funds are outside of the nursing home, they shall be returned within three banking days. The Department of Veterans Affairs states that the three banking days' requirement would be extremely difficult to accomplish if the funds are on deposit with the State Board of Investment. (Ex. S) The Broeker firm commented that the Department had not justified the three banking days' provision, and observed that five working days had been discussed before the Nursing Home Advisory Council. (Ex. GG, p. 12) Although the subsection is needed and reasonable as

proposed, the Department may wish to consider whether a change in regard to the number of banking days would result in a more workable rule.

30. Section 1.048 A.8.e. provides for the return of patient funds upon the death of a patient, and ends with the phrase "and shall return the funds to the appropriate individuals in accordance with state law". The MAHCF suggested that the language quoted be deleted since it is not necessary. (Tr. p. 90; Ex. FF, p. 6) The Department agreed to this suggestion. (Ex. 17, p. 6) With the deletion, the proposed rule subsection is needed and reasonable.

31. Section 1.048 A.8.f. provides that when a facility changes ownership, a written verification by a public accountant in regard to patient funds must be provided to the new licensee. The NHRA and the NHRAC (Tr. p. 84; Ex. EE, p. 2) felt that this verification should also be provided to residents. The Broeker firm pointed out that this proposed amendment suffered from vagueness since it was uncertain what should be included within a "verification" since this is not a term familiar to accountants. Furthermore, the term "public accountant" might be taken to exclude a CPA. (Tr. pp. 102-3; Ex. GG, p. 14) The Department agreed that the rule was undesirably vague and has proposed to withdraw this particular section since the changes it would wish to make are substantial.
(Ex, 17, p. 6)

Proposed Amendment to 7 MCAR § 1.046 L. - Use of Oxygen

32. This rule is proposed to be amended to permit the use of oxygen in nonemergency situations and to set up the procedures to be followed. The amendment, as proposed, received specific support. (Ex. Y, p. 1) Concern was expressed that since the use of oxygen sometimes means restrictions upon the patient, that patients still be allowed to participate in normal activities. (Tr. pp. 114-116; Ex. EE, p. 1) The Department noted that existing rules require that individual patient's plan of care be developed and revised to meet the individual needs of a patient. St. Benedict's requested that the Director of Staff Development be an alternative to the Director of Nursing in regard to training for administration of oxygen. (Ex. K, p. 1) The Department replied that the Director of Nursing is the proper person to be ultimately responsible. (Ex. 17, p. 7) The Broeker firm stated that it was not clear that Section 1.046 L.1.a. through d. also applied to nonemergency use of oxygen. (Ex. GG, p. 15) Although Section 1.046 L.2.c.(4) would seem to incorporate those requirements into the nonemergency section, it would probably be clearer should the first sentence of 46 L. read, "1. Oxygen, may be used in a nursing home on an emergency or nonemergency basis." The Broeker firm also requested that an emergency be defined so that the nursing home can determine when to apply the nonemergency part of the rule. (Tr. p. 117; Ex. GG, p. 15) The Department stated that the requirements of Section 2 need not be met until such time as a facility admits patients in need of oxygen as reflected in the written order of the physician and, therefore, such a definition is not necessary. (Ex. 17, p. 7) At the hearing, the Department proposed that a number "3" also be added to the new language in this proposed rule amendment, which would read as follows:

3. All oxygen used in the nursing home shall be from cylinders which bear labeling indicating that the oxygen is for medical purposes.

The rule, as amended, is needed and reasonable.

Proposed Amendment to 7 MCAR § 1.047 A. - Tuberculosis Testing of Employees

33. This rule is amended to continue testing of employees for tuberculosis, but to minimize the use of chest x-ray and to eliminate the annual requirement for testing of those employees who show a negative tuberculin test. Although the Broeker firm suggested that there were insufficient facts shown to support continued testing of employees for TB (Ex. GG, p. 16), the Department stated that 42.3% of the 175 cases of tuberculosis in 1978 occurred in individuals over age 65. Screening of nursing home residents and staff, therefore, is still recommended by the Department's tuberculosis screening unit, and is consistent with the recommendations of the American Thoracic Society and the Center for Disease Control. (Ex. 10, pp. 17-18; see also, Tr. pp. 127-28) Since the Department is merely amending the rule to provide different procedures, it is not required to establish once again the need for tuberculosis testing.

34. A new requirement in the rule is that the nursing home and boarding care home reimburse their employees for the costs of the tests required in the rule. The MAHA and the Broeker firm suggested that there was no rationale or facts presented to justify the facilities paying these expenses and urged deletion of the requirement. (Ex. J, p. 2; Tr. p. 126; Ex. GG, p. 16) The only rationale for this change provided by the Department was a single sentence in the Statement of Need which stated that, "Because the facility is responsible for assuring the testing, it is reasonable to require the nursing home to provide the testing or to reimburse its employees for the costs of obtaining the tests." (Ex. 10, p. 18) It does not appear that it necessarily follows that facilities should bear the costs merely because they are responsible for seeing that the testing is completed. Although it may very well be within the Department's statutory authority to promulgate this rule if it can be demonstrated that it is related to the welfare of patients, no facts or argument has been presented which would demonstrate that to be true. Accordingly, the Department has failed to make an affirmative presentation of facts showing the need for and reasonableness of requiring the facilities to pay the costs of tests.

35. Section 1.047 A.1. requires all employees to have a tuberculin test within 45 days prior to employment, unless a physician certifies a positive reaction. Two comments question the 45-day period as being unrealistic. (Ex. K, p. 1; Ex. Y, p. 1) The Department stated that a 45-day period is necessary due to the time delay from the time of infection to the point at which a skin test can identify an infection. (Ex. 17, p. 8) Two other comments (Ex. U, p. 1; Ex. CC, p. 2) questioned why a physician certification is necessary if an employee knows that he has a positive reaction. Dr. Terrence Henderson suggested that a statement of a past employer that the employee has a positive

reaction should be sufficient. The Department stated that a doctor certification prevents an employee, who is mistaken in his belief that he is a positive converter, from undergoing unnecessary x-rays and other tests. This rule subsection is needed and reasonable as proposed.

36. Section 1.047 A.1.b. requires that where the tuberculin test is positive, the employee must annually submit a report by a physician of a negative chest x-ray for five years. Dr. Henry B. Blumberg commented that the need for annual chest x-rays should be a matter for the individual personal physician to decide. (Ex. CC, p. 1) Dr. Terrence Henderson suggested a three-year limit for the chest x-rays in light of new knowledge concerning adverse effects of overexposure to x-rays. (Ex. CC, p. 3) The Department may consider these suggestions; however, the subsection is needed and reasonable as proposed.

Proposed Amendment to 7 MCAR § 1.049 C.1. - Patient Tuberculosis Screening

37. The Department proposes to amend this rule to require a chest x-ray within 45 days prior to admission for all patients. The existing rule requires a tuberculin test or if that test is positive, a chest x-ray within three months of admission. The Department states that the chest x-ray is substituted as the initial test upon the recommendation of the American Thoracic Society and the Center for Disease Control because an older person is less able to respond accurately to a tuberculin skin test. (Ex, 10, p. 22) Two comments (Ex. D; Ex. Y, p. 1) favored keeping the three-month provision. Dr. C. Dwight Townes noted that the Department's amendment is in line with the American Thoracic Society recommendation. (Ex. H) The Hazelden Foundation, which operates a 22-bed nursing unit, cited the increased expense and the hazard of x-rays as reasons for not promulgating this amendment. (Ex. T) The MAHCF pointed out that the patient bill of rights allowed a patient to refuse an x-ray and suggested that language be added to recognize this. (Tr. pp. 122-125) The Careview Home also cited the cost of the x-ray and questioned the need for a change from the tuberculin test. (Ex. U, p. 2) The Broeker firm questioned whether or not the Department had adequately supported its amendment.

38. An official statement of the American Thoracic Society in regard to screening for tuberculosis in institutions was attached to the Statement of Need as Exhibit D. The Statement notes that older persons admitted to nursing homes for long-term care have a higher prevalence of tuberculosis than the general population, and the institutional setting with persons grouped together increases the possibility of transmission of tuberculosis infection. The Statement also says that because there is a waning of tuberculin sensitivity with advancing age, the tuberculin test is not recommended as the initial screening test for older age groups. The Broeker firm suggests that the Department has not presented facts relating to the experience in the State of Minnesota, although the Statement of Need does indicate that 42% of the active tuberculosis cases in Minnesota in 1978 were in persons 65 and over. The statement of the American Thoracic Society says that screening programs should

be based on local data. It states that, "To determine the appropriate organization of the screening program in a given institution, it is necessary to know the incidence and prevalence of tuberculosis and tuberculosis infections in personnel and in persons served both in the institution and in the community from which they come. Data generated by the screening program should be used to evaluate and modify the program." The Department has not presented any data or argument to indicate that the tuberculin test has been ineffective or that the incidence of tuberculosis among nursing home personnel and residents in Minnesota would justify such a change. The Department has failed to adequately demonstrate the need for and reasonableness of this proposed change.

Proposed Amendment to 7 MCAR § 1.048 A.4. - Storage and Preservation of Records

39. The Department proposed to amend the period for retention of patient records following discharge or death from 10 years to five years. The Department stated that the 10-year period was unnecessary and burdensome in light of a lack of storage space in most facilities. (Ex. 10, p. 24) The amendment was supported by the MAHCF and the MAHA (Ex. FF, p. 6; Ex. J, p. 3) and others. (Ex. G) The Minnesota Medical Record Association pointed out that records are valuable in the study of geriatrics and chronic disease. (Tr. pp. 134-7) They recommended that the period be set at six years to coincide with the six-year statute of limitations in regard to contract actions. The examples cited by the Association, however, namely suits for injury or death resulting from an accident would appear to fall under the two-year statute of limitations at Minn. Stat. § 541.07, rather than under the contract statute of limitations at Minn. Stat. § 541.05. The proposed amendment has been shown to be needed and reasonable.

Proposed Amendment to 7 MCAR § 1.052 A.1. - Patient and Resident Units

40. This rule is proposed to be amended to eliminate the prohibition against the use of double beds and to require the facility to develop a written policy in regard to double beds. The LCRAR recommended suspension of the prohibition against the use of double beds. (Ex. 10, p. 31) The MAHCF supported the amendment. (Ex. FF, p. 6) The Careview Home questioned whether any rule or policy was needed in this area. (Ex. U, p. 2) The proposed amendment is needed and reasonable.

Proposed Amendment to 7 MCAR § 1.053 F. - Medications

41. This rule is proposed to be amended to conform with Board of Pharmacy Rule 7 MCAR § 8.032. The amendment to this rule will delete the mandatory destruction of unused drugs and permit their return to the dispensing pharmacy in accord with the Board of Pharmacy rule. The concept of eliminating the mandatory destruction of drugs was supported by Dr. Townes (Ex. H), Dr. M. L. Lohmann and Mrs. J. D. Ingersoll (Ex. X), Dr. Henderson (Ex. CC, p. 3) and the Pelican Lake Nursing Home. (Ex. Y, p. 1) The MAHA stated that the number of forms to be submitted could be limited by limiting the requirement to Schedule 2, 3, and 4 controlled substances. (Ex. J, p. 4; Tr. pp. 138-9) This would

apparently require a change to the Board of Pharmacy rule. The amendment is needed and reasonable as proposed.

Proposed Amendment to 7 MCAR § 1.055 U. - Dishwashing

42. This amendment is proposed to eliminate the prohibition against chemical sanitizing for dishwashing. In March of 1979, Economics Laboratory, Inc. submitted a formal petition for rulemaking in regard to the use of this type of dishwashing machine. The Department states that changes in technology have made low temperature dishwashing safer and acceptable for nursing homes. The MAHCF suggested that the first paragraph be amended to make it clear that either hot water or chemical sanitizing was permissible. (Ex. FF, p. 7) The Department agreed and suggested that the words "either of" be inserted after the words "shall conform with" in the first paragraph. (Ex. 17, p. 10)

43. In regard to Section 1.055 U.1.b.(1)(a), Economics Laboratory, Inc. suggested that the word "approved" was not appropriate. (Ex. P, p. 2) The Department agreed to rephrase the subsection to read as follows:

> Dishwashing machines using chemicals for sanitizing shall bear the seal indicating that the machine meets the standards of the National Sanitation Foundation. (Ex. 17, p. 10)

So amended, the proposed subsection is needed and reasonable.

44. 7 MCAR § 1.055 U.1.b.(1)(b) requires an audible signaling device when the detergent or chemical sanitizing supply is empty. Chemical Methods Associates, Inc. (Ex. E, p. 1) pointed out that a visual method should be an alternative in the rule. Economics Laboratory, Inc. stated that the National Sanitation Foundation Standard does not require a warning signal for detergent supply. (Ex. P, p. 2) The Department concurred in the suggestions and recommended that the subsection be revised as follows:

> Each dishwashing machine shall be equipped with a visual or audible signaling device which indicates when the chemical sanitizing supply is empty. The signaling device shall be maintained in an operating condition. (Ex. 17, p. 10)

So amended, the subsection is needed and reasonable.

45. Section 1.055 U.1.b.(1)(c) sets a pressure to be supplied for the final rinse water. Both Chemical Methods Associates, Inc. (Ex. E, p. 1) and Economic Laboratory, Inc. (Ex. P, p. 3) pointed out that all currently available commercial low temperature machines use a pump to provide a recirculating rinse and, therefore, are not dependent upon pressure of the external supply line. The Department agreed and proposed to withdraw this subsection. (Ex. 17, p. 10)

46. Section 1.055 U.1.b.(1)(d) requires the clean dish counter to provide space for at least four racks of dishes and utensils. The Department stated that counter space is necessary to assure proper air drying which is of particular concern with chemical sanitizing since the dishes are subjected to lower temperatures and take longer to dry. (Ex. 10, p. 35) Chemical Methods Associates, Inc. commented that the primary factors in the drying rate are temperature and humidity, and that humidity is usually lower when chemical sanitizing is used. They believe that this requirement is not justifiable since it would tend to limit the use of chemical sanitizing dishwashers. (Ex.

E, p. 2) Economic Laboratory, Inc. commented that specifying the number of racks is too rigid and suggested rephrasing the rule by stating that the clean dish counter be adequate to provide a two-minute drying time per rack. (Ex. P, p. 3) Although the rule is needed and reasonable as proposed, the Department is encouraged to consider the suggestions of Economic Laboratory, Inc. so as to avoid excluding machines which fall within the spirit but not the exact language of the rule.

47. Section 1.055 U.1.b.(2)(d) sets a minimum rinse water temperature. Economic Laboratory, Inc. proposed that the term "chemical manufacturer" be changed to "machine manufacturer". (Ex. P, p. 4) The Department agreed and suggested that the subsection be reworded as follows:

> The chemical sanitizing rinse water temperature should not be less than 75 degrees Fahrenheit (24 degrees centigrade) nor less than the temperature specified by the machine manufacturer as indicated on the NSF data plate.

The subsection is needed and reasonable as amended.

48. Section 1.055 U.1.b.(2)(f)(i) requires the concentration level to be tested "each time the machine is used". Chemical Methods Associates, Inc., Economics Laboratory, Inc., and the Anoka County Director of Environmental Services (Ex. E, p. 2; Ex. P, p. 4; Ex. C, p. 1) all found the quoted phrase ambiguous and impractical if it means a test after each cycle of the machine. The Department agreed and suggested that the word "time" be replaced by the word "day". So amended, the proposed subsection is needed and reasonable.

Proposed Amendment to 7 MCAR § 1.064 A.3.f.(1) - Bedroom Doors

49. The existing rule prohibits locks on patient room doors. The LCRAR recommended suspension of the existing rule. The proposed amendment requires the nursing home to develop a written policy regarding locks and describes the type of lock which may be used so that for safety purposes the door can be opened from the inside at all times without a key. The Residents Council of the Halstad Memorial Home stated that they believed that locks were not necessary (Ex. B), and St. Benedict's commented that locks present a difficulty from a fire safety standpoint. (Ex. K, p. 2) The MAHCF commented that the language in B, stating that the door can be "locked only from the corridor side" might be interpreted to not permit the resident to lock the door from the inside. The Department should examine a clarification in this regard. The proposed amendment is needed and reasonable.

Proposed 7 MCAR § 1.044 X. - Variance in Waivers

50. This proposed rule will set up a procedure for granting variances and waivers which the Department believes is necessary where complete compliance with the rules is not possible. (Ex. 10, p. 4) The MAHA (Ex. J, p. 4) and the MAHCF both supported the concept of a waiver and variance rule. (Ex. FF, p. 7) The NHRAC opposed any waiver for the minimal daily dietary requirements or the patients bill of rights. (Ex. EE, p. 1) The Broeker firm and the MAHCF raised several items which they believed were not addressed in the proposed rule and should be. (Ex. GG, pp. 19-21, 23; Ex. FF, p. 7) One concern is the effect of a waiver request in a later enforcement proceeding; namely,

whether or not the request can be used to prove a violation. Another concern is whether or not a penalty may accrue even though a variance or waiver request is pending before the Department. It was also requested that should a waiver be denied, the facility should then have a period of time for correction subsequent to the denial. Both the Broeker firm and the MAHCF suggested amendments to be added to the rule which would make it clear that a request for a waiver is not an admission and that no fine would accrue while a request is pending. (Ex. FF, Amendment No. 3 and 4) Although the proposed rule is not rendered unreasonable by the failure to include these items, the Department may consider their inclusion since these are decisions which will have to be made by the Department at some point in time. As the Department points out, however, they may be enforcement decisions depending upon the circumstances of particular cases and it might also properly be the subject of later rulemaking based on the enforcement experience.

51. Section 1.044 X.2.d. requires a request for variance to include the length of time for which it is requested. Both the Broeker firm and the MAHCF suggested that the Department should consider criteria by which to evaluate the length of time or to consider when a waiver should be permanent. (Ex. FF, p. 8; Ex. GG, p. 21) The subsection is needed and reasonable as proposed.

52. Section 1.044 X.2.e. allows the Department to obtain from the applicant such other relevant information which "the Department shall determine is necessary to properly evaluate the request". The Broeker firm again raised the question of what would happen if the Department makes such a request and the nursing home is in the process of assembling the material while the time period for the correction order runs out. The Broeker firm also suggested that the possibility of an oral presentation should be included in the rule. (Tr. pp. 169-170, 172) Although the rule subsection is needed and reasonable as proposed, the Department should limit the discretion given to it in the proposed rule by eliminating the language "which the Department shall determine is" or indicating by the addition of language that only information necessary to comply with this rule may be requested.

53. Section 1.044 X.3.a. sets out the criteria for evaluation of a request. The Broeker firm and the MAHCF both noted that because of the way the rule is structured, the Department would have to make an affirmative finding in regard to each of the three criteria before a variance or waiver could be granted. (Ex. FF, p. 8; Ex. GG, pp. 21-22; Tr. pp. 155, 172) This creates a problem since alternative measures are sometimes not possible and an innovative approach to a nursing home problem might not necessarily impose an undue burden upon a nursing home. The Department agreed that the problem existed and suggested that the subsection be amended as follows:

> a. The decision to grant or deny a variance or waiver shall be based on the Department's evaluation of the following criteria:
>
> 1. The variance or waiver will not adversely affect the health, treatment, comfort, safety or well being of a patient or resident;
>
> 2. The alternative measure to be taken, if any, are equivalent or superior to those prescribed in the rule; and

3. Compliance with the rule or rules would impose an undue burden upon the applicant.

The Department believes that this proposed language will provide the flexibility to handle situations where a particular criterion is not applicable. (Ex. 17, p. 12) So amended, this subsection is needed and reasonable.

54. Section 1.044 X.4. provides that alternative measures attached to a variance may be the subject of correction orders and shall have the same time period for correction as the rule for which the variance was granted. The MAHCF and the Broeker firm (Tr. pp. 157-8; Ex. FF, p. 9; Ex. GG, p. 22) stated that it was not reasonable to automatically apply to the alternative measure the same period of time for correction in the rule where the alternative measures require action that is different in scope or nature than the actions necessary to comply with the rule. The MAHCF suggested that the following language be added to the end of this subsection: "unless the alternative measures necessitate actions different in scope or nature from the actions necessary to comply with the literal requirements of the rule". (Ex. FF, Amendment No. 6) Although the subsection as proposed cannot be said to be unreasonable or arbitrary, the Department should consider the addition of some language similar to that proposed by the MAHCF so that a time period and fine appropriate for the violation is arrived at.

55. Section 1.044 X.5.a. requires a request for renewal of a variance to be in writing and submitted prior to the expiration of the variance. The MAHCF suggested that the rule is too rigid since it does not provide for the situation where a facility finds out the day before the expiration of its variance that it cannot apply. (Tr. pp. 159-61; Ex. FF, p. 9) They suggested deleting the phrase "prior to its expiration date" so that a request could be submitted after expiration. The Department stated that this requirement is necessary to be informed as to the continued need for a variance. (Ex. 17, p. 13) Enforcement would be difficult if a facility was able to request renewal at any time after expiration. The subsection is needed and reasonable as proposed.

56. Section 1.044 X.5.b. provides that the variance may be renewed if the criteria continues to be satisfied and the applicant continues to comply with alternative measures or conditions imposed. At the hearing, the Department proposed to replace "may" with "shall". (Ex. 13, p. 1) The Broeker firm questioned how the applicant was to demonstrate compliance with alternative measures and stated that the vagueness in this phrase rendered the rule unreasonable. (Ex. GG, p. 23; Tr. pp. 173-175) The Department stated that what it seeks is assurances in terms of what the facility has done to specifically comply with the alternative measures. (Tr. pp. 174-175) The subsection is needed and reasonable as proposed and amended.

57. Section 1.044 X.6. provides that an applicant shall be notified in writing of a decision to deny, revoke or refuse to renew a variance or waiver. The MAHCF and the Broeker firm stated that it was necessary that the reasons for the denial be stated by the Department and also stated that a time limit should be set by which the Department must make its decision. (Tr. pp.

161-162; Ex. FF, p. 9; Ex. GG, p. 23) The Department agreed as to the need for a statement of reasons and suggested that the last sentence read as follows:

> The applicant shall be notified in writing of the decision to deny, revoke or refuse to renew the variance or waiver, informed of the reasons for the denial, revocation or refusal to renew, and informed of the right to appeal this decision. (Ex. 17, p. 13)

The Nursing Home Advisory Council had suggested a 30-day time limit which the MAHCF suggests is particularly necessary if a request for a waiver does not stay the accrual of fines. Although the proposed subsection is needed and reasonable as amended, the Department should consider the inclusion of a time period for decision in order to make the the entire waiver rule more workable.

58. Section 1.044 X.7. sets out the appeal procedure and provides that the applicant must appeal within 15 days of receipt of the Department's decision and places the burden of proving that it has satisfied the criteria upon the applicant. The MAHCF commented that the 15-day period was too short and suggested that a 20-day period be substituted. (Tr. p. 163) The Broeker firm questioned whether or not the burden of proof ought to be placed on the applicant. (Ex. GG, p. 23) The Department replied that this is appropriate since the applicant is in the best position to demonstrate that the criteria have been met. The Department cited the case of In re Application of the City of White Bear Lake, 247 N.W.2d 901, 904 (1976) as authority for the proposition that generally an applicant has the burden of proof. The Department accurately states the law except in regard to the revocation of a variance or waiver. Generally the proponent of certain action being taken is the party which has the burden of proof, and generally when an agency seeks to revoke a license, a permit or a waiver which it has granted, it will then have the burden of proof. See, 1 Cooper, State Administrative Law, Ch. 12, § 1 (1965). The Department should amend this section to exclude the revocation situation from the general rule as to the burden of proof.

Proposed Amendment of 7 MCAR § 1.057 A., B. and C. - Schedule of Fines

59. Section 1.057 C. sets out the schedule of fines for the other rules which are being promulgated in this rule hearing proceeding. The fines accrue daily in accordance with Minn. Stat. § 144A.10, subd. 6, which provides that a nursing home "shall be assessed a civil fine in accordance with the schedule of fines promulgated by rule of the Commissioner of Health. A 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. . . ." The Department has authority to assess fines up to $250 per day, and has divided the schedule of fines into three levels of assessment at $50, $150 and $250. The three levels are based on the degree of harm that would result if the nursing home fails to comply with the rule in question. The Department stated that:

> A $50 penalty assessment will be issued for a violation of these rules which have only a minimal relationship to the health, safety, treatment, comfort or well being of a patient in the nursing home. A violation of these rules would not create a

situation which would jeopardize the health or safety of a patient. A $150 penalty assessment will be issued for a violation of those rules which could potentially create a situation jeopardizing the health, safety, treatment, comfort or well being of the patient. A $250 penalty assessment will be issued for a violation of these rules which would create a situation jeopardizing the health, safety, treatment, comfort or well being of the patients. (Ex. 10, p. 40)

At the hearing, the Department proposed adding one more rule subsection to C.2. of the rule to read as follows:

Z. 7 MCAR § 1.046 L.3. (Ex. 13, p. 1)

The proposed rule including the provisions for three levels of fines, daily fines and a $50 minimum fine were supported by the FRNHR (Ex. BB), the Metropolitan Senior Federation (Tr. pp. 232-4) and the Minnesota Board on Aging (Tr. pp. 235-6). The MAHCF and the Broeker firm each stated that a $50 per day fine was too high for a violation which only minimally affects the health or safety of a patient. (Tr. pp. 192-195; Ex. GG, p. 24) They stated that the Department had failed to justify the reasonableness of the $50 minimum fine as opposed to a system which permits either a more flexible assignment of fines or a fixed daily fine less than $50. The Department pointed out that a recent Hennepin County District Court decision found the mandatory predetermined administrative fine constitutional and suggested that it in fact avoided some problems since it maintained uniformity and avoided discrimination. (Ex. 16) The Department also stated that violations which have a minimal relationship to patient health or safety does not necessarily equate to a de minimus violation in the OSHA area, as was suggested by the MAHCF. (Tr. p. 202) The Department's position is that the three levels including the $50 minimum per day fine provide a rational basis for the issuance of assessments, especially since prior to the issuance of a fine, the nursing home is fully informed as to the nature of the deficiencies and provided a period of time in which to make the necessary corrections. Only where a facility has failed to comply with the correction order and, where upon reinspection the Department determines the facility is still in noncompliance will a fine then be assessed. (Ex. 10, p. 40) The proposed rule has been demonstrated to be needed and reasonable.

60. The MAHCF and the Broeker firm raised several other important questions relating to the operation of this rule and the statute. (Ex. FF, pp. 10-20; Ex. GG, p. 24) The most serious issue raised is the question of whether or not fines continue to accrue on a daily basis in regard to an assessment when an appeal has been taken and not yet decided. The Broeker firm and the MAHCF believe that if this is the Department's interpretation, then the system is unconstitutional since there is no opportunity for a hearing before the fine, and the daily penalty is so burdensome in its cumulative effect that a facility is effectively permitted from appealing the matter. The MAHCF believes that the statute does not mandate daily accrual of fines based on the interpretation that a facility is not in violation or in noncompliance unless it has failed to appeal or appealed an assessment and lost. (Ex. R) Another remedy proposed by the MAHCF would be that the Department allow an appeal from the issuance of a correction order prior to the assessment of a fine.

61. Although the facility raised serious questions in regard to the procedure to be followed, a careful consideration of all of the materials submitted leads to the conclusion that the MAHCF's dispute is with the statute rather than the proposed rule. The statute mandates a daily fine. The only provision in the statute for a stay of an assessed fine is in regard to its recovery rather than in regard to its accrual. Minn. Stat. § 144A.10, subd. 6 through 8 appears to contemplate the accrual of fines during an appeal and it would appear to be questionable whether the Department could properly promulgate a rule which provided otherwise. The constitutionality of the system which is established by the statute in regard to correction orders, inspections and fines of nursing homes must be resolved by a court of law. The matter has already once been the subject of litigation. The proposed rule is not unreasonable by reason of its failure to speak to the matter of accrual of fines during an appeal since the question is answered by the statute.

7 MCAR § 1.058 - Allowable Time Periods for Correction

62. This is a new rule proposed by the Department to satisfy the statutory mandate to establish a schedule of allowable time periods for correction of deficiencies. The rule will apply only to the rules which are being promulgated in this rulemaking proceeding. The Department offered three amendments at the hearing; namely, adding the following to Section 1.058 A.1.:

g. L.3. 30 days

and in regard to Section 1.058 A.7.c., changing the 14 days to 30 days and correcting a typographical error in Section 1.058 B.3.a.(2)(a) in the word "supplies". (Ex. 13, p. 1; Ex. 17, p. 2) The allowable time periods for correction were divided by the Department into three categories; namely, 14 days, 30 days and 60 days. The 14-day period is used for those rules which can be easily corrected by a facility utilizing the internal resources of the nursing home such as those orders which can be corrected by the development of internal policies. The 30-day period is utilized for those rules that were possibly capable of being corrected through the utilization of nursing home resources, but would usually require some contacts with individuals outside of the facility. A 60-day time limit is reserved for those specific rules where outside resources would generally have to be contacted such as the purchasing of equipment or the obtaining of contracts. The Department notes that where the nursing home can demonstrate that the time period is not sufficient, it can request an extension from the Department. (Ex. 10, pp. 55-57)

63. The MAHCF suggested that these time periods should be minimums only and suggested that language be added to the first paragraph of the rule permitting the surveyor to set a longer period where he finds unique circumstances. (Ex. FF, p. 20) The Broeker firm stated that the Department's presentation did not contain any experience, facts or alternatives to support the assignment of the different periods to various rules. (Ex. GG, p. 30) More specifically, they suggested that a change in internal policies may require more than 14 days where a patient care committee must be convened and also that violations of the dishwashing rules may require outside help and

therefore require more than 14 days. (Tr. p. 257-63) The Department has adequately demonstrated the need for and reasonablenes of Section 1.058 A. Although the Department has not discussed individual instances of its experience with the time periods for correction in the past, it would appear that the reasoning and conclusions contained in the Statement of Need are necessarily based upon that experience.

64. Section 1.058 B.1. provides that the nursing home administrator may request an extension which must be received by the Department prior to the expiration of the time period for correction. The MAHCF suggested that requiring that the request be received prior to the expiration of the time period in the correction order would encourage unnecessary filing by facilities. They propose that the last two sentences of the rule subsection be deleted. (Tr. p. 250; Ex. FF, p. 21) The Broeker firm stated that the failure to submit a request within the time period should not always automatically result in a denial and should be subject to a good cause exception. The firm also saw a need for a period of time after denial to allow for correction. (Tr. p. 267; Ex. GG, pp. 30-31) The Broeker firm also suggested that the rule should state that persons other than the administrator can request the extension. (Tr. pp. 263-64)

65. In response to the last suggestion, the Department suggested that the words "administrator of" be deleted from the proposed rule subsection so that "the nursing home" requests an extension. The Department stated that the automatic denial upon a failure to timely request an extension is necessary to assure prompt compliance by facilities. (Ex. 17, p. 16) It is a mechanism to assure that facilities will not delay in making efforts to attain compliance based on an assumption that they could always request an extension at some time in the future. The subsection is, as amended, needed and reasonable.

66. Section 1.058 B.2.a.(6) provides that the Department can request "such other relevant information which the Department shall determine is necessary". The prior comment in regard to this type of language at Finding of Fact No. 51 should apply here also.

67. Section 1.058 B.2.b. requires that an oral request for extension be confirmed in writing within 24 hours. The Broeker firm suggested that the requirement should be one working day so as to avoid a problem with weekends. (Ex. GG, p. 31) The Department may consider this request; although, since the rule as proposed appears to merely require the administrator to place the written request into the mail, it is needed and reasonable.

68. Section 1.058 B.5. provides that the Department shall give its reasons for denial of any request for extension in writing. The MAHCF suggests that the denial of a request for extension will give rise to a contested case under Chapter 15 and that the rule should so state similar to the appeal procedure in the variance and waiver section. It has suggested proposed language which would require an applicant to submit a written request for hearing within 15 days of the receipt of the denial. (Ex. FF, Amendment No. 12) Although the proposed rule is not arbitrary for a failure to set out the requested language, the Department may consider its inclusion. The subsection is needed and reasonable as proposed.

69. General support of all of the proposed rules was expressed by the Executive Director of the Legislative Commission to Review Administrative Rules (Tr. pp. 59-60), and by the Metropolitan Senior Federation (Tr. p. 67)

Based upon the foregoing Findings of Fact, the Hearing Examiner makes the following:

CONCLUSIONS

1. That the Department of Health gave proper notice of the promulgation of the proposed rules and rule amendments.

2. That the Department of Health has statutory authority to promulgate the proposed rules and rule amendments.

3. That the Department of Health has, with the exceptions noted at Findings of Fact Nos. 52, 58 and 66, fulfilled all relevant substantive and procedural requirements of law or rule.

4. That the Department of Health, with the exceptions noted at Findings of Fact Nos. 34 and 38, has demonstrated the need for and the reasonableness of the proposed rule amendments by an affirmative presentation of facts in the record.

5. That a finding of need and reasonableness or compliance with Chapter 15 in regard to any particular rule amendment should not preclude or discourage the Department from further modification of the language based upon an examination of the public comment, provided that no substantial change is made from the rules as originally proposed and provided that the rule finally adopted is based upon facts appearing in the record.

Based upon the foregoing Conclusions, the Hearing Examiner makes the following:

RECOMMENDATION

It is recommended that the proposed rule amendments be adopted as modified by the Findings of Fact and Conclusions set out herein.

Dated: May 20 , 1980.



GEORGE A. BECK
State Hearing Examiner

ADMIN 1000 (Rev. 1/78)
SF-00006-01

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

TO : Jerry Anderson
Special Assistant Attorney General
Administrative Division

DATE: October 9, 1980

FROM : John A. Breviu
Special Assistant
Attorney General

PHONE: 341-7272

SUBJECT: In the Matter of Proposed Amendments Relating to Rules For the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes

I have enclosed the original hearing record plus one copy of the following documents for your review in the above-referenced matter pursuant to Minn. Stat. § 15.0412:

1. Order of the Chief Hearing Examiner;
2. Findings of Fact, Conclusions and Order of the Commissioner of Health;
3. Rules as Adopted by the Commissioner; (3 copies)
4. Rules as Proposed (posthearing changes are marked in red);
5. Report of the Hearing Examiner;
6. Statement of Need and Reasonableness;
7. Notice of Intent to Obtain Information on Proposed Rules from Non-agency Sources;
8. Proposed Rules Published in the State Register;
9. Order for Hearing;
10. Notice of Hearing as Mailed;
11. Affidavit of Receipt of the Secretary of State's List;
12. Certificate of the Secretary of State;
13. Affidavit of Mailing of the Notice of Hearing; and
14. Certificate of Compliance with Rule Making Procedures.

JAB:ejg

Enclosures

RECEIVED
OCT 1 0 198
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

SF-00006-01

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT Attorney General's Office

TO : Judith Wehrwein
Attorney General's Office
Department of Administration

DATE: October 23, 1980

FROM : John Breviu
Special Assistant Attorney General
Health Law Division

PHONE: 341-7272

SUBJECT: Nursing Home Rules

As we discussed, I contacted Health Department staff regarding the errors in the copy of the Rules as Adopted. I am enclosing the corrected pages 12, 20, 22, 23 and 24. In addition, the renumbering of the items on page 20 necessitated changes in page 21, a copy of which is also enclosed. Department staff asked that I convey their appreciation for your thoroughness.

RECEIVED
OCT 23 1980
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

BROEKER, HARTFELDT, HEDGES & GRANT
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EILEEN M. ROBERTS

October 20, 1980

Mr. Theodore Grindal
Special Assistant Attorney General
G25 Administration Building
50 Sherburne Avenue
St. Paul, Minnesota 55155

Re: In the Matter of the Adoption of Rules Relating to the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Home and Boarding Care Homes

Dear Mr. Grindal:

We are submitting the following comments in the above-entitled matter pursuant to Attorney General 305(c). Although not representing any specific clients for purposes of the rulemaking hearing, we nevertheless had considerable input both at the April 1, 1980, hearing and subsequently in written comments, as a large proportion of our practice is in the area of long term care. These comments will focus on only a few of the issues raised at hearing and in written comments to the Hearing Examiner and the Commissioner, but we ask that in your review you refer to our earlier input for a more complete discussion of the issues raised here and for a discussion of other matters not raised here for the sake of economy. We have enclosed copies of our letter of April 21, 1980, to the Hearing Examiner and of our letter of May 29, 1980, to the Commissioner of Health for your easy reference. Whenever possible, these comments will make specific references to the relevant arguments in our earlier comments.

A. Attorney General Review as to Adequacy of the Record.

Many of our earlier comments dealt with the failure of the Department of Health (hereinafter "Department") to adequately support its proposals with an affirmative presentation of facts showing the need for and reasonableness of the specific proposals and with an adequate statement of the anticipated costs and benefits of each proposal as required by Minn. Stat. §144A.29, subd. 4 (1978).

We refer you to pp. 1-3, 10-15, 27-30, 32 of our April 21, 1980, letter for more complete discussions some of which have been heeded by the Department in its adopted rules; here only very few of those issues will be focused on by way of example.

1. Statement of Anticipated Costs and Benefits.

The Department has failed to comply with the duties imposed upon it by Minn. Stat. §144A.29, subd. 4 (1978) and thus the record is inadequate to support final adoption of several of the rules. That statute provides:

> "Each rule promulgated by the commissioner of health pursuant to Section 144A.01 to 144A.17 shall contain a short statement of the anticipated costs and benefits to be derived from the provisions of the rule."

The Department has failed to comply with that provision in at least three respects.

First, it has interpreted the term "costs" in the statute to apply only to nursing home costs, not to potential costs to the Minnesota Medical Assistance budget through increased rates or charges, to the Department itself for monitoring compliance and to private residents. In a time of budget deficiencies, inflation and concern about the cost of health care, it is unquestionable that potential increases in costs to one agency by rules of another must be addressed, not to mention increased costs to individual residents. See p. 2 of our April 21, 1980, letter.

Second, the Department has refused to make an estimate of the anticipated costs and benefits of any provisions it considered "non-mandatory", notwithstanding the fact that there is no doubt that those provisions will be implemented and that some estimate could be made. The Hearing Examiner, while upholding the Department's Statement of Anticipated Costs and Benefits in its entirety, did conclude that the Department's rationale for failing to make as comprehensive an analysis as possible frustrated the purpose of the statute:

> "It is clear, however, that it was intended that the Department should weigh costs against benefits in the process of rule promulgation. This goal is frustrated when the Department's effort stops at simply stating that a rule is

> not mandatory and, therefore, costs cannot be estimated. The spirit of the statute should require the Department to estimate what costs it believes will actually result. This would include an estimate as to how many facilities will comply or take advantage of the proposed rule. The record in this matter suggests that whether or not the federal regulations are promulgated, a large number of facilities would choose to handle patient funds under this proposed rule, and the Department could have made an estimate of the cost to the nursing home."

Finding of Fact No. 13, p. 5, Report of Hearing Examiner, May 20, 1980.

The Commissioner's response to that observation (at pp. 1-2 of his October 7, 1980, Findings of Fact, Conclusions and Order Adopting Rules) is inadequate and the handling of patients' and residents' funds provisions of the proposed rules as addressed by the Hearing Examiner are a very good example. Federal regulations which were to have become effective on October 22, 1980, mandated the handling of patient funds for all Minnesota nursing homes other than the one or two who do not participate in the Medical Assistance program. Yet the Commissioner has persisted in saying, in an ostrich-like manner, that

> "The enactment of those rules would not, per se, result in any additional costs to a nursing home or boarding care home. Costs would only be incurred when a decision would be made by facility personnel to offer a particular service. Since the Department is not in the position to either ascertain with any reasonable accuracy, the number of facilities that would elect to provide a service . . .."

Findings of Fact No. 2. To the contrary, the Commissioner could in fact estimate quite well how many facilities would be affected by the proposed 7 MCAR §1.048 A.8., but will not and has not, and thus has not fulfilled the requirements of Minn. Stat. §144A.29, subd. 4.

We would also note that those proposed federal regulations have recently been suspended by the Department of Health and Human Services pending further review because the Office of Management and Budget has concluded that they are unnecessarily onerous and

costly. As the Commissioner himself notes in his Findings that the proposed state regulations are similar to and compatible with the federal regulations, these regulations may also be too onerous and costly. The Department's refusal to undertake any cost estimates because they are allegedly "non-mandatory" does not provide anyone with the ability to make that vital assessment.

Third, a balancing or comparison of the costs and benefits has not in each case been undertaken. The most glaring example of this deficiency in the Department's approach is in its statement in purported justification of the manner in which it chose to implement the daily fine system, 7 MCAR §1.057 C . A major change in the enforcement mechanism for nursing home standards is being implemented in accordance with Minn. Stat. §144A.10 which authorizes a daily fine anywhere between $0 and $250 per day. Yet, when the Department makes the actual choice of figures to be applied, it made no attempt to analyze and compare the benefits to be derived from the proposed system in relationship to the potentially high cost of its proposal. For example, a $50 daily accruing fine, the minimum fine for violations with a "minimal relationship to the health, safety, treatment, comfort or well-being" under the new system, could accrue up to $18,000 per year, yet nowhere is the purported benefit of increased deterrence against potential violations of "minimal relationship" measured against that extraordinarily high potential cost. Deterrence may be an important component of the daily fine system but some attempt at balancing the cost of that deterrence to the benefit to be gained must be made. It may very well be that a much smaller minimum daily fine would be a very effective deterrent for minor violations of regulations, yet not have the potential for such severe and disproportionate financial impact, but the Department has failed to make any analysis whatsoever along those lines. Such an analysis is particularly important when the same minor violations are presently subject to a one time $50 or $250 fine and no contention is made by the Department that fines of that size are not currently effective deterrents.

See also p. 29 of our April 21, 1980, letter for further discussion. The $50 daily fine is used only as an example of deficiencies in support of the entire system proposed by the Department.

2. Statement of Need and Reasonableness.

The Department's Statement of Need and Reasonableness and presentation at hearing has failed in several respects to adequately support its proposals. Again, the most glaring example

is in the Department's lack of justification for the choice it made in implementing the daily fine system of 7 MCAR §1.057 C. A more complete discussion of these deficiencies is found at pp. 27-28 of our April 21, 1980, letter but the basic deficiency is the failure to present facts justifying its choice of a $50, $150 and $250 three tier system. Asked if he could comment on the reasoning behind the figures actually picked to implement a statute which allows great flexibility in fines between $0 and $250, the Department witness stated:

> "I don't know if there really is a response to that." T. 192.

The Statement of Need and Reasonableness is no more comprehensive in discussing the facts or reasoning behind the choice made and we urge you to carefully review the record for adequacy of support of the choices made in implementing the statute.

See also pp. 11-15, 29-30, of our April 21, 1980, letter for other examples of similar deficiencies in other areas of the proposed rules.

B. Attorney General Review as to Legality.

In the interests of economy, we will not repeat the substance of our earlier comments which also indicate that the standards of Atty. Gen. 305(b)(2) have not been met. However, the failure to meet the requirements of Minn. Stat. §144A.29, subd. 4 quite clearly means that the proposed rules "Exceeds the statutory authority conferred or the required conditions have not been met". Atty. Gen. 305(b)(2)(aa). The failure to justify with facts or reasoning the choices made in implementing Minn. Stat. §144A.10 through the choices set forth in 7 MCAR §1.057C. indicates that there is no "reasonable relationship to statutory purposes" and that the rules are "unconstitutional, arbitrary or unreasonable". Atty. Gen. 305(b)(2)(cc) and (dd). We also refer to pp. 24-27 of our April 21, 1980, letter for additional discussions of the respects in which the Department's proposals do not meet basic principles of fairness, common sense and due process, all leading to a conclusion that the daily fine system as implemented by the Department is unconstitutional.

We have commented previously that some of the Department's proposals go beyond the statutory authority to promulgate "minimum standards". Minn. Stat. §144A.08, subd. 1. A particular example are the patient and resident fund proposals, 7 MCAR §1.048 A.8.

The Commissioner himself stated that those regulations are similar to and consistent with federal regulations recently determined to be too onerous by the Office of Management and Budget. We urge careful review of these rules for provisions which are beyond minimum standards. See also p. 11 of our April 21, 1980, letter.

C. Attorney General Review as to Form.

1. The use of the word "attributable" in proposed 7 MCAR §1.048 A.8.c.6. is unenforceably imprecise and vague. See pp. 14-15 of our April 21, 1980, letter.

2. The lack of thorough guidance to either the Department or nursing homes on the question of how to deal with the personal funds of incompetent patients who do not have legal guardians gives unnecessary and unacceptable discretion to the Department in its enforcement of the provisions of 7 MCAR §1.048 A.8. Notwithstanding the Department's addition of the term "representative payee" to the rules after hearing, the Commissioner himself noted that there will be instances in which none of the enumerated representatives will exist and in which the rules themselves provide no standards. Reliance on federal regulations to fill gaps in state rules and enforcement of state rules is not sufficient, particularly when those federal regulations have been suspended. See p. 14, paragraph 8 of our April 21, 1980, letter.

We ask your careful review of all issues previously raised, even though not addressed here for the sake of brevity. We will be happy to amplify our comments in any way you may find useful and are eager to answer any questions you may have.

Very truly yours,

BROEKER, HARTFELDT, HEDGES & GRANT

By Barbara J. Blumer
Barbara J. Blumer

BJB:jlh
Enclosures

MINNESOTA ASSOCIATION OF HEALTH CARE FACILITIES

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TELEPHONE: 612/854-2844

October 21, 1980

RECEIVED
OCT 22 1980
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

Mr. Jerry Anderson
Assistant Attorney General
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St. Paul, MN 55155

RE: In the Matter of Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes.
HLTH -80-040-GB
Order dated October 7, 1980

Dear Mr. Anderson:

Pursuant to Minnesota Statutes §15.0412, Subd.4e, and Rule 305 of the Rules of the Office of the Attorney General, the Minnesota Association of Health Care Facilities wishes to question the legality of the above-captioned rules. Along with the arguments herein, I have enclosed for your convenience a copy of our comments to the Hearing Examiner in this matter.

Because of the extremely serious constitutional questions raised by the Department's rule establishing a daily fining system (7 MCAR §1.057), and because of the relative complexity of the operation of this system, we believe it would be helpful to the Attorney General in carrying out his statutory duty to approve or disapprove the rules, to hear oral arguments on the issues we raise. Therefore, in addition to these written comments, we hereby request an opportunity for oral argument as well.

Rule 305(b)(2) of the Rules of the Office of the Attorney General provides:

"(2) Regarding legality, the rule shall be disapproved if it:

(aa) Exceeds the statutory authority conferred or the required conditions have not been met.

(bb) Conflicts with the governing statute or other relevant law.

(cc) Has no reasonable relationship to statutory purposes.

(dd) Is unconsitutional, arbitrary or unreasonable." (emphasis added)

There are several provisions of the proposed rules of the Department of Health which, under the above-cited criteria, mandate their disapproval by the Attorney General. We would like to comment upon five specific provisions which raise the most serious problems.

7 MCAR §1.057 Sechedule of Fines

By adopting this rule, the Department of Health purports to be implementing Minnesota Statutes §144A.10. The rule as adopted mandates that nursing homes that are issued correction orders with which they do not comply will be fined either $50, $150, or $250 "on a daily basis". This procedure raises several serious questions of reasonableness and constitutionality.

One critical issue relates to whether or not the Department will accrue the fines on a daily basis even when an appeal has been taken from an assessment. At the hearing the Department refused to answer this question (T. 182-183),* and yet the issue is important not only in itself, but it also affects the reasonableness of other provisions such as the amount of daily fines, the allowable time periods for correction, the operation of the waiver system, and others. The statute is almost four years old and the Department certainly must have considered this issue. We believe that, whatever the policy is, it should be clearly spelled out in the rule to give nursing homes reasonable notice of how the system will work.

The Department indicated, in response to our question, that this was a question of statutory interpretation and therefore is not relevant to the adoption of the proposed rules (T. 181). We agree that it is a matter of statutory interpretation, but strongly disagree that it is not relevant. As we pointed out above, this question affects any decision regarding the reasonableness of other rules. Also, we believe that whatever the Department's position is on the question of accrual of fines during an appeal, it is and should be

*Subsequent to the hearing, the Department finally did state that it would accrue the fines on a daily basis even during a good faith appeal from an assessment. See letter of April 18, 1980 from Janet Brodahl to K. Craig Wildfang, attached to letter of April 21, 1980 from Janet Brodahl to Mr. George Beck (MHD's post-hearing comments).

a rule. Minn. Stat. §15.0411, Subd. 3 states

> "'Rule' includes every agency statement of general applicability and future effect, including the amendment, suspension, or repeal thereof, made to implement or make specific the law enforced or administered by it or to govern its organization or procedure . . ."

In establishing a policy on this question, the Department is promulgating a rule, and that rule should be tested by the processes outlined in the Administrative Procedures Act just as are the other rules.

The Minnesota Association of Health Care Facilties believes that §144A.10, on which the Department is relying in promulgating a schedule of fines, does not mandate the daily accrual of fines when a good faith appeal has been filed. Understanding the meaning of §144A.10 is complicated by the lack of definitions for some very important terms. Two of the more important undefined terms are "violation" and "noncompliance". Both of these terms are used in §144A.10 in respect to correction orders. They are, in effect, legal conclusions. Once a facility is found to be in "violation", or in "noncompliance", then certain results follow under the statute. The important question, however, is: When, and under what circumstances, is a facility in "violation" or in "noncompliance"? The answer should be that a facility falls into those categories when one of two situations exist; either (1) the facility was issued an assessment and did not appeal it, in which case the allegation in the assessment is conceded to be true, or (2) the facility appealed from an assessment and lost the appeal. The third possible situation is where a facility receives an assessment and then appeals from the assessment. In such a situation the allegation in the assessment is immediately placed in doubt, as a legal matter. Once a facility has filed an appeal, the Department bears the burden of proving, by a preponderance of the evidence, that the facility is in "violation" or "noncompliance", see 9 MCAR §2.217.c.5. Therefore, it cannot be said that a facility that has appealed from an assessment is, in fact, in "violation" or "noncompliance". To do so would be inconsistent with the Administrative Procedures Act and the rules promulgated pursuant thereto, and would, we believe, be a denial of due process as well.

It is in this framework, then, that we can look at the language of subdivision 5, 6, 7 and 8 of §144A.10. Subdivision 5 provides:

> Subd. 5. Reinspections. A nursing home issued a correction order under this section shall be reinspected at the end of the period allowed for correction. The reinspection may be made in

> conjunction with the next annual inspection or any other scheduled inspection. If upon reinspection the representative of the commissioner of health determines that the facility has not corrected a violation indentified in the correction order, a notice of noncompliance by certified mail to the nursing home. The notice shall specify the violations not corrected and the fines assessed in accordance with subdivision 6. (emphasis added)

Again, a facility may only be said to be in "violation" or "noncompliance" if it has either not appealed the assessment, or has appealed and lost. If the facility has an appeal pending then the allegations in the assessment are in doubt, and the facility is only in violation or in noncompliance after the Department has proven it by a preponderance of the evidence.

Subdivision 6 is the most important in understanding the statute. It provides:

> Subd. 6. Fines. 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 promulgated by rule of the commissioner of health. The fine shall be assessed for each day the facility remains in noncompliance and until a notice of correction is received by the commission or health in accordance with subdivison 7. No fine for a specific violation may exceed $250 per day of noncompliance. (emphasis supplied)

As the underlined sentence makes clear, for a facility to be assessed a daily fine, two criteria must be met: (1) the facility must be in "noncompliance" and (2) the facility must have failed to give a notice of correction. As pointed out above, if the facility has appealed from an assessment, it cannot be said to be in noncompliance while the appeal is pending because the whole point of the appeal is to determine that question.

The Department, in a meeting on March 19, indicated the belief that subdivisions 7 and 8 supported an interpretation that §144A.10 mandated daily accrual of fines even during an appeal. We do not believe that is true if the appropriate meanings are given to the terms "violation" and "noncompliance" as outlined above. Subdivision 7 deals with the accumulation of fines and subdivision 8 deals with the recovery of assessed fines. Both of these subdivisions are based on the presumption that a valid fine has been or is being assessed pursuant to subdivision 6. Under the construction that we urge, no

valid fine may be assessed under subdivision 6 when an appeal has been filed, and therefore subdivisions 7 and 8 do not support the daily accrual of fines during an appeal.

We believe that the interpretation of §144A.10 outlined above is a reasonable and appropriate one, one that does not saddle the Department with an unworkable and unfair tagging system, and one that meets the requirements of due process.

If the Department's apparent intention to accrue fines on a daily basis even during a good faith appeal is implemented, not only will the system be unreasonable, unfair and unworkable, it will also be unconstitutional. An understanding of how this new system would operate is essential to understanding its constitutional defects. Under this new system, a nursing home might be inspected by the regular surveyors (or the Office of Health Facility Complaints) and might be issued a correction order for the violation of a rule. The correction order would be based on the surveyor's observations and on his or her interpretations of the rule and of the facts of the situation. The nursing home would be given a specific period of time in which to correct the alleged deficiency (e.g., 30 days). At this point, under current Department policy, the facility cannot appeal the correction order, even if the correction order is totally in error. On Day 30, the facility will be issued an assessment if, according to the surveyor, the alleged deficiency has not been corrected, and the fine begins accruing. Only then may the facility appeal, once the fine has already begun accruing. Obviously, at $50, $150, or $250 a day, very few facilities will want to risk filing an appeal, no matter how meritorious.

When this system is analyzed in light of basic constitutional principles, it is clearly unconstitutional. The basic principles of due process of law require that an individual be afforded the opportunity to be heard before a penalty or fine is assessed against that individual. Furthermore, no penalty can be of such a nature so as to effectively deprive an individual of the right to be heard. The general rule may be stated as follows:

> "Where penalties prescribed for a violation of a statute or of a state constitution are of so extreme a character as probably to prevent resort to the courts to test the validity of a statute or the constitution, there is a lack of due process of law; and a statute which provides such penalties for noncompliance with an administrative order or regulation must afford reasonable opportunity to test the validity of the order or regulation in the courts." 16 Am. Jur. 2d Constitutional Law, §640.

Basic constitutional guarantees of due process and the right to petition for a redress of grievances are found in both the United States and Minnesota constitutions. The Fourteenth Amendment to the United States Constitution, applicable to the states and subdivisions thereof, provides that:

> "No State shall make or enforce any law which shall abridge the privileges of immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jursidiction the equal protection of the laws."

Art. 1, §7 of the Minesota Constitution (Restructured-1974) also guarantees due process of law to the citizens of the State of Minnesota. As is guaranteed under the First Amendment to the United States Constitution, the State of Minnesota has guaranteed to its citizens the right to redress of grievances. In Art.1, §8 of the Minnesota Constitution (Restructured-1974):

> "Every person is entitled to a certain remedy in the laws for all injuries or wrongs which he may receive to his person, property or character, and to obtain justice freely and without purchase, completely and without denial, promptly and without delay, conformable to the laws."

The penalty system provided under the system envisioned by the Department effectively denies an individual or nursing home or boarding care facility the opportunity to contest a fine because of the prohibitive effect of a cumulative fine. Given the present backlog in the courts of the State of Minnesota and delays incurred through the Office of Hearing Examiners, it is conceivable that a final determination would not be obtained for a number of years, during which time a fine would continue to accrue. A $250 fine accrued over one year for example, would amount to over $90,000. With this kind of threat it is difficult to see how any facility would challenge any fine, no matter how unjust. And it is indisputable that many fines in the past have been improperly imposed.

One of the leading cases striking down a lesser penalty system similar to the scheme found in Section 10 is Oklahoma Operating Co. v. Love, 252 U.S. 331, 40 S. Ct. 338, 64 L. Ed. 596 (1920). An order of the Oklahoma Corporation Commission prohibited plaintiff therein from raising its rates on the ground that the laundry business conducted by plaintiff was in the nature of a public business, and thus the rates charged were subject to approval by the Commission. Plaintiff operated under this scheme for a few years, but then raised its rates without approval of the Commission. As a result of his actions, plaintiff became subject to contempt proceedings. Furthermore,

plaintiff was subject to a $500 per day fine for its failure or refusal to obey an order of the Commission.

The original order of the Commission declaring plaintiff a public business was made after notice and hearing, as was the order assessing the daily fine. As an aside, no hearing would be provided under the Department's system before a fine is assessed and begins to accrue. Although the order originally declaring plaintiff a public business was subject to appeal directly to the Oklahoma Supreme Court, rate orders could not be so appealed. The rate could be appealed or contested only in conjunction with a contempt porceeding for failure to comply with the rate order. An appeal to the Supreme Court was conditioned upon the filing of a surety bond in double the amount of the fine assessed, with the bond suspending the fine.

The Oklahoma scheme was struck down forcefully by the United States Court as being in violation of due process of the law. The Court stated that the limited method of appeal, coupled with the daily fines, effectively deprived plaintiff of its right to be heard:

> "But the penalties, which may possibly be imposed, if he pursues this course without success, are such as might well deter even the boldest and most confident . . . Obviously a judicial review beset by such deterrents does not satisfy the constitutional requirements, even if otherwise adequate, and therefore the provisions of the acts relating to the enforcement of the rates by penalties are unconstitutional without regard to the question of the sufficiency of those rates." 252 U.S. at 336-337.

A similar decision on an analogous situation made on the same day is Oklahoma Gin Co. v. State of Oklahoma, 252 U.S. 339, 40 S.Ct. 341, 64 L.Ed. (1920).

The scheme the Department apparently intends to implement is more onerous than that found in the above Oklahoma cases. At least in the Oklahoma cases, the original orders declaring a business to be a public business were issued following notice and hearing. The initial order was immediately appealable, although the rate-setting orders of the Commission were not. In the case at hand, correction orders and notices of non-compliance, giving rise to fines, are issued merely upon the determination of an employee of the Health Department to do so. There is no opportunity for a hearing until after the daily fine begins to accrue. The Minnesota scheme is more violative of due process than the scheme at issue in the Oklahoma cases.

A 1971 Ninth Circuit decision struck down a penalty system

under which fines of up to $1000 per day per violation could be assessed. In United States v. Pacific Coast European Conference, 451 F.2d 712 (CA 9 1971), the Court had occasion to review a 1961 act which prohibited, for the most part, a dual rate contract system used in international shipping. Defendants challenged the uniform contract that was required, if not in form then at least in substance, by the Federal Maritime Commission. The Commission attempted to assess fines against the defendants for periods extending from April 4, 1964, through December 31, 1966, at which time defendants came into compliance with the statute.

The District Court granted summary judgment for defendants on the issue of the penalty. Defendants based their motions for summary relief on:

> "'the constitutional principle, established by a long line of Supreme Court cases, that statutory penalties cannot lawfully attach during the period of a bona fide judical review of a legislative act, whether statute or administrative agency ruling.'" 451 F.2d at 715-716.

Although the District Court did not state its basis in arriving at the ruling favorable to defendants, the Appellate Court assumed that it was on the ground urged by defendants.

In its discussion upholding the action of the District Court, the Ninth Circuit examined the "tolling doctrine" and its purposes. The Court cited a 1915 United States Supreme Court case, Wadley v. Southern Railway Company v. Georgia, 235 U.S. 651, 35 S.Ct. 214, 59 L.Ed. 405 (1915), in which a $5000 per day statutory penalty was declared invalid. The Ninth Circuit decision quotes extensively from Wadley, and it is appropriate to here restate part of the Wadley opinion.

> "A statute therefore which imposes heavy penalties for violation of commands of an unascertained quality, is in its nature, somewhat akin to an ex post facto law since it punishes for an act done when the legality of the command has not been authoritatively determined. Liability to a penalty for violation of such orders, before their validity has been determined, would put the party affected in a position where he himself must at his own risk pass upon the question. He must either obey what may finally be held to be a void order, or disobey what may ultimately be held to be a lawful

> order. If a statute could constitutionally impose heavy penalties for violation of commands of such disputable and uncertain legality the result inevitably would be that the carrier would yield to void orders, rather than risk the enormous cumulative or confiscatory punishment that might be imposed if they should thereafter be declared to be valid." 235 U.S. at 662-663.

The Court was, of course, concerned with frivolous attacks on statutes or administrative rules in an attempt to evade the assessed penalty. The Court stated that even though a statute or order is upheld on review, such does not make an appeal frivolous and thus cause the reimposition of the penalty. The right to test the validity of a statute or administrative order is to be judged, not by an after-the-fact determination, "but by whether defendants mounted a substantial attack upon the validity of the statute and order." 451 F.2d at 719. The Wadley Court went on to state that even partial impairment of "judicial review protected by the tolling doctrine" [i.e., tolling of assessment during review] is "impermissible" 451 F.2d at 719. Clearly the system envisioned by the Department will substantially impair the right to judicial review by making such review extremely and unreasonably costly.

The Wadley case cited above also traces through pre-1914 federal and state court decisions in which penalty schemes were found to deprive an individual of due process of law or equal protection of the law by effectively prohibiting resort to test the validity or reasonableness of an order or fine. See, for example, Mercantile Trust Co. v. Texas & Pac. Ry., 51 Fed. Rep. 529(4), 549 (14-15) (1892); Cotting v. Kansas City Stockyards Co., 183 U.S. 79-101, 22 S.Ct. 30, 46 L.Ed. 92 (1901); Ex parte Young, 209 U.S. 123, 28 S.Ct. 441, 52 L.Ed. 714 (1908); Minnesota Rate cases, 230 U.S. 352, 472, 473, 33 S.Ct. 729, 57 L.Ed. 1511 (1913); Missouri Pacific Ry. v. Nebraska, 217 U.S. 196, 207,30 S.Ct. 461, 54 L.Ed. 727 (1910); Missouri Pacific Ry. v. Tucker, 230 U.S. 340, 349, 33 S.Ct. 961, 57 L.Ed. 1507 (1913); Bonnett v. Vallier, 136 Wes. 193 (15,16) (1908); and Coal and Coke Ry. v. Conley, 67 W.Va. 129, 132, 67 S.E. 613 (1910).

A more recent case re-stated the rule set down by Young, Wadley, Love and St. Regis line of cases. In Brown & Williamson Tobacco Corp. v. Engman, 527 F.2d 115 (2 Cir 1975), cert. den. 426 U.S. 911 (1976), the Court stated that these cases

> "establish that one has a due process right to contest the validity of a legislative or administrative order affecting his affiars without neccessrily having to face ruinous penalties if the suit is lost." 527 F.2d at 1119 (original emphasis)

It is clear that if the Department implements the system as they apparently intend, this rule will be violated. A nursing home will be faced with ruinous penalties if an appeal to contest the validity of an assessment is lost. By permitting a penalty scheme under which daily fines of up to $250 would accrue, the Department of Health is effectively depriving individuals of their right or opportunity to be heard. Cases cited above clearly show that the imposition of cumulative daily fines are of such an oppressive and burdensome nature so as to effectively preclude the opportunity of an individual to be heard.

At the hearing Mr. Breviu asked if we were seeking to have the hearing examiner declare the statute unconstitutional and we replied that we are not. Obviously a hearing examiner does not have the same authority as a court of law to do so. However, we do beleive that a hearing examiner may examine and comment upon the constitutionality of a scheme as it relates to the reasonableness of a proposed rule. This is especially true where the statute does not clearly mandate the unconstitutional scheme. Further, we believe that a rule which results in an unconstitutional system is per se unreasonable and should not be adopted.

It is clear that the Attorney General, pursuant to the statute and rules cited herein, shall disapprove a rule which violates constitutional guarantees. Under the cases cited above there can be no substantial doubt that a fining system which mandates a $250 per day fine even during a good faith appeal, violates the Due Process Clause of the Fourteenth Amendment.

The Department is faced with implementing a statute which is subject to at least two interpretations. As outlined earlier, we believe that it may be interpreted to avoid the daily accrual of fines while an appeal is pending, and thereby avoiding an unconstitutional scheme. Minn. Stat. §645.17 establishes certain statutory presumptions in ascertaining legislative intent. This section provides

> "In ascertaining the intention of the legislature the courts may be guided by the following presumptions:
>
> . . .
>
> (3) The legislature does not intend to violate the constitution of the United States or of this state;
>
> . . .

Although the Department is not necessarily bound by this

statutory presumption to the same extent that courts are, we believe the logic behind the presumption applies with equal force when the Department is interpreting and implementing a statute. That is, the Department should strive to avoid an unconstitutional result, if possible. We believe that the Attorney General should disapprove the rule unless it is amended to allow the accruing of the fine to be stayed during the pendency of a good faith appeal.

Another question which we raised at the hearing deserves some additional comment. Given the current system for issuing correction orders and assessments, and given the impact of the new daily fining schedule, we asked whether the Department considered changing their procedure to allow for appeals from correction orders rather than being forced to wait for an assessment. At one time the Department did allow for appeals from correction orders. As with the question relating to daily accrual, the question of appeals from correction orders affects the reasonableness of the rules governing the amount of fines, the time period for correction, and others. Also, as with the question of daily accrual, the Department's current policy of not allowing appeals from correction orders is not mandated by the statute. Again, this is an area where the Department could change their policy and establish a more reasonable rule. Even if the Department's apparent position that daily accrual during an appeal is mandated by law is upheld, allowing appeals from correction orders coupled with a procedure granting an extension of time for compliance when a facility files a good faith appeal might perhaps save the system from unconstitutionality.

As we stated at the hearing, we seriously question the reasonableness of any system that imposes a $50 daily penalty assessment (which amounts to $18,250 over a year's time) for the violation of a rule which the Department concedes bears "only a minimal relationship to the health, safety, treatment, comfort or well-being of a patient in a nursing home" (Statement of Need and Reasonableness, page 40). From the Department's response to questions at the hearing (T. 192-193), it is clear that the Department has not satisfied its burden of establishing facts demonstrating the reasonableness of $50/$150/$250 fine schedule. The Department admitted that they did not consider other types of fining schemes such as OSHA (T. 193). The OSHA system, for example, does not impose any fine for a de minimus violation. The Department did not give any facts that demonstrated that a 3-tier system is more reasonable than a 10-tier system, or a flexible system as was proposed in 1977. We believe that not only did the Department fail to meet its burden of showing the reasonableness of the proposed fine schedule, but that the fine schedule is patently unreasonable in light of the Department's position on the other issues we have raised.

7 MCAR §1.044 Variance & Waiver

There are three features of this rule that are clearly arbitrary and unreasonable and which should cause the Attorney General to disapprove the rule.

The first of these is the lack of a provision guaranteeing that a request for a variance or waiver of a rule will not be used by the Department in a later enforcement hearing as an admission that the facility was not in compliance with the rule that was sought to be waived. The Department refused to include such a provision in the rule and insisted that the Department retained the option to use such a waiver request as an admission, at least in some cases (see Commissioner's Findings of Fact, Conclusions and Order Adopting Rules at pp. 9-10). This will result in a facility being forced to make an impossible choice between asking for a waiver when one is necessary while knowing that the request itself might be the basis for a correction order or fine and not seeking a waiver and running the risk of being cited for non-compliance anyway. This situation is so unfair as to render the rule arbitrary and unreasonable.

In regard to 7 MCAR §1.044.X.4., we would reiterate our comments made at the hearing that there may be situations in which it is unreasonable to automatically apply to the alternative measure the same period of time for correction and amount of fines as those for the particular rule which is being waived. There may be cases where the alternative measures necessitate action that is different in scope or different in nature than the actions that might be taken to comply with the literal requirements of the rule. The criteria that the Department used in proposing a 14 day, 30 day, or 60 day time period for compliance with particular rules might suggest a different time period for certain alternative measures. Again, the result of this provision is a rule that is arbitrary and unreasonable.

In regard to §1.044.X.5a, we believe that requiring requests for a renewal of a waiver/variance to be sumitted prior to the expiration date is unnecessary and unreasonable. It may lead to the routine request for renewals which are not necessary, as a way for facilities to "cover" themselves against some unforeseen, last-minute problem. This rule, also, is arbitrary and unreasonable.

7 MCAR §1.058 Time Periods for Correction

In §1.058.B.1., the Department is again attempting to require the submission of requests for an extension of time to comply with a correction order prior to the expiration of the time period cited in the correction order. We went to great lengths to explain to the

Department that the inflexible enforcement of this rule might lead to facilities routinely requesting extensions, whether they are necessary or not, simply in order to protect themselves against some unforeseen problem that might arise on the day the period for correction expires. This rule is unnecessary, and therefore is arbitrary and unreasonable.

We hope the Attorney General will carefully consider our arguments herein. The disapproval of these rules on the bases we have suggested will enable the Department to correct certain features which will lead to better and more fair rules. The defects in the rule could be remedied quickly and easily by the Department, and the Attorney General should require this before approving these rules.

Very truly yours,

K. Craig Wildfang
Staff Counsel

KCW/arr
cc: Commissioner George Petterson

Our File # [redacted]
643.

Permanent Rule_____

Temporary Rule_____

RULES REVIEW CHECKLIST

DATE RULES RECEIVED 10/10/80 DUE DATE 10/30/80

Resubmitted and Received_____

a. Returned to Agency w/o Filing w/Secretary of State_____
b. Approved_____ Date Sent Back to Agency_____

- -

1. Rules as Adopted ✓
2. Rules as Proposed ✓
3. Certificate of Board's Authorizing Resolution, where applicable N/A
4. Order for Hearing ✓
5. Notice of Hearing ✓ 11.1.80
   Sufficiency ✓ but see HE 8+9 re fiscal note
6. Secretary of State's List ✓ (one copy only)
7. Certificate of Acquisition of Secretary of State's List ✓
8. Secretary of State's Certification of Delivery of Secretary of State's List to Agency ✓
9. Affidavit of Mailing ✓
   At least 30 days prior to hearing ✓ 2.26.80
10. Publication in State Register ✓ Notice of Errata ✓ ✓ 3.17.80
    At least 30 days prior to hearing ✓ 2.25.80
11. Statement of Need and Evidence ✓
12. Hearing Examiner's Report ✓
13. Agency's Findings of Fact A) ✓ 10.7.80 B) Amendment to, 10.9.80 combined with #15 – Order Adopting
14. Certificate of Board's Resolution Adopting Rules, where applicable N/A
15. Order Adopting A) ✓ 10.7.80 B) Amendment to, 10.9.80
16. Report of Chief Hearing Examiner ✓
17. Order Approving Incorporation by Reference, where applicable N/A
18. Certificate of Compliance with Rulemaking Procedures ✓
19. Copy of Notice of Intent to Solicit Outside Opinion, where applicable ✓ 11.8.76 !
20. Petition by Public, where applicable ✓ plus attachments

Rules as Proposed.

7 MCAR § 1.044 ~~MHB-44~~ Definitions, general provisions, issuance of licenses.

X. Variance and waivers.

1. General provisions. A nursing home or boarding care home may request that the Department grant a variance or waiver from the provisions of these rules.

2. Contents of request. All requests for a variance or waiver shall be submitted to the Department in writing. Each request shall contain the following information:

a. The specific rule or rules for which the variance or waiver is requested;

b. The reasons for the request;

c. The alternative measures that will be taken if a variance or waiver is granted;

d. The length of time for which the variance or waiver is requested;

e. Such other relevant information ~~which the Department shall determine~~ ~~is~~ necessary to properly evaluate the request for the variance or waiver.

3. Criteria for evaluation.

* The decision to grant or deny a variance or waiver shall be based on the Department's evaluation of the following criteria:

a. ~~A variance or waiver shall be granted if the Department determines that:~~

(1) The variance or waiver will not adversely affect the health, treatment, comfort, safety or well-being of a patient or resident; ~~The alternative measures to be taken are equivalent or superior to those prescribed in the rule or rules;~~

(2) The alternative measures to be taken, if any, are equivalent to or superior to those prescribed in the rules; and ~~The granting of the variance or waiver will not adversely affect the health, treatment, comfort, safety or well-being of the patients or residents; and~~

(3) Compliance with the rule or rules would impose an undue burden upon the applicant. ~~The application of the rule or rules would impose an undue burden upon the applicant.~~

b. The applicant shall be notified in writing of the Department's decision. If a variance or waiver is granted, the notification shall specify the

Change-E Report - F#52 + Conc #3 - adopted by Commissioner

* - Post-hearing ~~amendment~~ by the Department, adopted by H.E. - F# 53 and adopted by Commissioner of Health.

period of time for which the variance or waiver will be effective and the alternative measures or conditions, if any, to be met by the applicant.

4. Effect of alternative measures or conditions. All alternative measures or conditions attached to a variance or waiver shall have the force and effect of the licensure rule(s) and shall be subject to the issuance of correction orders and penalty assessments in accordance with the provisions of Minn. Stat. 144.653 and 144A.10. The period of time for correction and the amount of fines specified for the particular rule for which the variance or waiver was requested, shall apply.

5. Renewal.

a. Any request for the renewal of a variance or waiver shall be submitted in writing prior to its expiration date. Renewal requests shall contain the information specified in section 2. above.

Hearing Amendment by Dept. accepted by H.E. - F # 56 adopted by Commissioner

b. A variance or waiver ~~may~~ shall be renewed by the Department if the applicant continues to satisfy the criteria contained in section 3. above and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance or waiver was granted.

6. Denial, revocation or refusal to renew. The Department shall deny, revoke or refuse to renew a variance or waiver if it is determined that the criteria specified in section 3. above are not met. The applicant shall be notified in writing of the decision to deny, revoke or refuse to renew and informed of the right to appeal this decision.

Post hearing Amendment - accepted by H.E. F # 57 - adopted by Comm

the variance and waiver, informed of the reasons for the denial, revocation or refusal to renew

7. Appeal procedure. An applicant may contest the denial, revocation or refusal to renew a variance or waiver by requesting a contested case hearing under the provisions of the Administrative Procedures Act, Minnesota Statutes, § 15.0411 et. seq. The applicant shall submit, within 15 days of the receipt of the Department's decision, a written request for a hearing. The request for hearing shall set forth

in detail the reasons why the applicant contends the decision of the Department should be reversed or modified. At the hearing, the applicant shall have the burden of proving that it satisfied the criteria specified in section 3. above, except in a proceeding challenging the revocation of a variance or waiver.

Amendment required by Hearing Examiner, H.E. F #58 and Conclusion #3

7 MCAR § 1.046 ~~MHD-46~~ General policies.

HE suggestion F #32

L. ~~(1)~~ Use of oxygen.

1. Oxygen, ~~when~~ may be used in a nursing home ~~shall be~~ on an emergency or nonemergency basis. ~~only. The oxygen shall be ordered by a physician.~~ A registered nurse or other person trained in the use of oxygen shall be responsible for its administration and shall be on duty during the entire time that oxygen is administered. The following precautions shall be taken:

a. ~~(1)~~ Signs indicating "No Smoking" shall be placed at the bedside and at the entrance to the room.

b. ~~(2)~~ All matches, ash trays and other smoking material shall be removed and kept out of the room.

c. ~~(3)~~ No oil or grease shall be used on oxygen equipment.

d. ~~(4)~~ Oxygen tanks shall be securely anchored when stored or in use.

2. A nursing home, which admits or retains patients in need of oxygen, on other than an emergency basis, shall comply with the following provisions:

a. The nursing home shall provide 24 hour licensed nurse coverage, unless it only admits patients who can self-administer oxygen.

b. The patient's attending physician shall submit written orders for oxygen and, if self-administration of oxygen is also ordered, the physician shall specify that the patient is mentally and physically capable of administering oxygen without the assistance of the nursing home staff.

c. The Patient Care Policy Committee shall develop and implement written policies regarding the provision of oxygen in the nursing home. These policies shall, at a minimum, include:

(1) Any limitations placed on the patient or other patients such as room assignments and smoking policies.

(2) Any restrictions placed on patients using portable oxygen equipment as to mobility within the facility or participation in activities.

(3) A mechanism to periodically assess those patients authorized to self-administer oxygen as to their continued capability to self-administer it.

(4) Precautions to be taken, in addition to those in section 1.a.-d., above, to assure the safe use of oxygen.

d. All nursing homes which admit patients in need of oxygen, shall inform these patients of any limitations or restrictions imposed by the nursing home prior to admission or at the time the use of oxygen is ordered by the physician.

e. The director of nursing shall be responsible for providing training to the nursing home staff regarding the procedures to be followed for the administration of oxygen, for monitoring the use and effectiveness of oxygen, special precautions to be taken, and the care and cleaning of equipment.

f. Written policies and procedures shall be developed and implemented regarding the care, storage, cleaning and sanitizing of oxygen ~~tanks~~, equipment and supplies.

Commissioner's Finding # 18

3. All oxygen used in the nursing home shall be from ~~cyl~~ cylinders which bear labelling indicating that the oxygen is for medical purposes.

Hearing amendment - accepted by H-E F# 32 - adopted by Commissioner.

7 MCAR § 1.047 ~~MHD-47~~ Personnel.

A. ~~(a) Annual Tests.--All employees shall, prior to employment and annually thereafter, show freedom from tuberculosis by a report of either a standard Mantoux tuberculin test or a chest X-ray.--If the Mantoux test is positive or contraindicated, a chest X-ray shall be taken.--The results of these tests shall be reported in writing and made a part of the employee's personnel record.--(See Personnel Records, under Records and Reports, MHD-48.)~~ Tuberculosis testing of employees. The nursing home or boarding care home shall be responsible for assuring that all employees, prior to employment and as otherwise indicated in this rule, show freedom from tuberculosis in accordance with the provisions of this section. ~~The nursing home and the boarding care home shall reimburse their employees for the costs, if any, of obtaining the necessary tests which demonstrate freedom from tuberculosis.~~ Deletion required by H.E. F #34 + C #4

1. All employees, unless certified in writing by a physician to have had a positive reaction to a standard intradermal tuberculin test, shall have a standard intradermal tuberculin test with purified protein derivative (Mantoux) within 45 days prior to employment.

a. If the tuberculin test is negative, the employee shall be considered free from tuberculosis.

b. If the tuberculin test is positive or if the employee's physician has certified a positive reaction to the tuberculin test, the employee shall submit prior to employment and annually thereafter, a written report by a physician of a negative full-sized chest X-ray taken within the previous 45 days. Annual written reports of the employee's negative chest X-ray shall be required for five years after a documented positive standard intradermal tuberculin test, after which time the employee shall be considered free from tuberculosis.

2. All employees showing positive reaction to the tuberculin test who have taken a complete course of preventive therapy as directed by their physician,

shall be considered free from tuberculosis at the completion of the program and shall be exempt from the testing requirements of this section.

3. Written documentation of compliance with the above requirements shall be filed in the employee's personnel record.

7 MCAR § 1.048 ~~MHD~~-48 Records and reports.

(APPLIES TO BOTH NURSING HOMES AND BOARDING CARE HOMES)

A. ~~(a)~~ Patient or Resident Care Record. An individual chart shall be kept on each patient and resident admitted to the home. All entries shall be made with a pen and signed by the person making the entry. Accurate, complete and legible records for each patient or resident from the time of admission to the time of discharge or death shall be kept current and shall be maintained in a chart holder at the nurses' or attendants' station.[1]

1. ~~(1)~~ Admission Record. The admission record shall be initiated for each patient and resident within 72 hours after admission and contain identifying information including: name, previous address, social security number, sex, marital status, age, date and place of birth, previous occupation, date and hour of admission; name, address and telephone number of the nearest relative, and the person to be notified in an emergency or death; information as to funeral arrangements, if available; church affiliation and pastor; and the name of the patient's or resident's attending physician. At the time of discharge or death, this record shall be completed with the date, time, reason for discharge, discharge diagnosis and condition; or date, time and cause of death. In either case the signature and address of the responsible person to whom released shall be obtained.

2. ~~(2)~~ Medical Record. The medical record shall be initiated for each patient or resident within 72 hours in accordance with MHD 49 (c).

3. ~~(3)~~ Filing and Disposition of Records. The patient or resident care record shall be incorporated into an individual folder and filed at the nurses' or attendants' station.[1] The records of discharged patients or residents shall be promptly completed and filed in the home.

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[1] A central control point for the storage of records and medications.

Patients' or residents' medical records and patient care plans in nursing homes shall be considered confidential but they shall be made available to all persons in the home who are responsible for the care of the patient or resident and they shall be open to inspection by representatives of the Department. When a patient or resident is discharged to another care facility pertinent information relative to his care shall accompany the patient or resident.

4. ~~(4)~~ Storage and Preservation of Records. Space shall be provided for the safe storage of patients' or residents' records at the nurses' or attendants' station[1] and in general storage. Records shall be filed so as to be readily accessible. All patients' and residents' records shall be preserved for a period of at least ~~ten (10)~~ 5 years following discharge or death.

5. ~~(5)~~ Census Register. A register shall be kept in a separate bound book, listing in chronological order the names and dates of all admissions and discharges. This register shall be kept in such a manner that total admissions, discharges, deaths and patient or resident days can be calculated.

6. ~~(6)~~ Reports to the Department. Reports regarding statistical data and services furnished shall be submitted on forms furnished by the Department. Copies shall be retained by the home.

7. ~~(7)~~ Correspondence with Department. All correspondence with the Department shall be kept as a permanent, accessible record.

8. ~~(8)~~ Record of Patients' and Residents' Funds. ~~The home shall keep a record of any personal funds, regardless of source, and of any valuables kept for a patient or resident. If purchases are made from these personal funds, proper receipts shall be kept and notations made in a separate bookkeeping system.~~

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[1] A central control point for the storage of records and medications.

Post-hearing amendment by Dept accepted by H.E. F # 19, adopted by Commissioner

a. Admission ~~Agreement~~ Policy. The admission policies of the nursing home and boarding care home shall specify whether the home will accept the personal funds of patients' or residents' for safekeeping. If the nursing home or boarding care home accepts the personal funds of patients' and residents' for safekeeping, written policies regarding the handling and protection of the funds shall be established in accordance with this section.

b. Authorization.

(1) The personal funds of the patient or resident shall not be accepted for safekeeping without written authorization from the patient or resident or from the patient's or resident's legal guardian or conservator or representative payee.

(2) A copy of this written authorization shall be retained in the patient's or resident's records. Commissioner's Finding # 7

(3) A "representative payee" is an individual designated by the Social Security Administration to receive benefits on behalf of the patient or resident.

c. Personal Fund Accounts

(1) The personal funds of patients' and residents' shall not be commingled with the funds of the nursing home or boarding care home or with the funds of any person other than patients or residents of the home, unless otherwise authorized by law. Commissioner Finding # 8

(2) The personal funds of patients' and residents' shall not be used in any way for the purpose of the nursing home, boarding care home or any other patient or resident and shall be free from any liability that the nursing home or boarding care home incurs.

(3) A person, firm, partnership, association or corporation which operates more than one facility licensed in accordance with the provisions of Minnesota Statutes § 144.50-.56 or Minnesota Statutes, Chapter 144A shall not commingle patient or resident funds from one facility with another.

(4) A written accounting system for the personal funds of patients and residents shall be developed and maintained.

(a) Each patient or resident and the patient's or resident's guardian, conservator, or other person designated by the patient or resident shall be allowed access to the written records of all financial arrangements and transactions involving the individual patient's or resident's funds in accordance with the nursing home's and boarding care home's written policy. Such policy shall assure that access be ~~allowed at least one hour 5 days per week~~.

(b) Each patient or resident or the patient's or resident's guardian, conservator, or other person designated in writing by the patient or resident, shall be ~~provided~~ a written quarterly accounting of the financial transactions made by or on behalf of the patient or resident.

(c) An individual written record shall be maintained for each patient or resident which shall include the following items:

(i) The date, amount and source of funds deposited by or on behalf of a patient or resident.

(ii) The name of all individuals, other than the patient or resident, authorized to withdraw or expend funds from the patient's or resident's personal account.

(iii) The date and the amount of all withdrawals from the patient's or resident's personal account. ~~Receipts for purchases made with money withdrawn from a patient's or resident's account by individuals other than the patient or resident shall be obtained and placed in the patient's or resident's record.~~

(5) The personal funds of any patient or resident in excess of $100.00 shall be deposited in a demand account in a financial institution authorized

to do business in Minnesota, the deposits of which are federally insured, except that a facility that is operated by a county shall deposit such funds with the county treasurer. This account must be in a form which clearly indicates that the facility has only a fiduciary interest in the funds. Records shall be maintained which specify on whose behalf funds are deposited or withdrawn from this account.

(6) If a patient's or resident's personal funds are deposited in an interest bearing account, the accrued interest shall, unless otherwise specified by law, be prorated in accordance with the amounts attributable to each patient or resident and recorded on the patient's or resident's account.

Post hearing amendment accepted by HE, F # 14 + adopted

(7) Upon the request of the patient or resident or the patient's or resident's legal guardian or conservator or representative payee, (Commissioner's F # 1) the nursing home or boarding care home shall return all or any part of the patient's or resident's funds given to the nursing home or boarding care home for safekeeping, including interest, if any, accrued from deposits. The nursing home or boarding care home shall develop a policy specifying the period of time ~~for each day of the week that funds can be withdrawn~~ during which funds can be withdrawn each day of the week. - Hearing amendment - accepted by HE, F # 28 + adopted ~~drawn~~. Funds kept outside of the facility shall be returned within ~~three banking~~ five business days. Commissioner's Finding # 15

d. Discharge of Patient or Resident. Upon discharge of a patient or resident, unless the patient's or resident's bed is being held for anticipated readmission, all funds of that patient or resident shall be returned to the patient or resident or to ~~an authorized individual~~ the patient's or resident's legal guardian a conservator, representative payee or other person designated by the patient or resident, with a written accounting, in exchange for a signed receipt. Funds which are maintained outside of the nursing home or boarding care home shall be returned within ~~three banking~~ five business days. Commissioner's Finding # 15 Commissioner's Finding # 17

e. Death of a Patient or Resident. Upon the death of a patient or resident, the nursing home or boarding care home shall provide a complete accounting

Post-hearing amendment, accepted by H.E # 30 + adopted

of that patient's or resident's funds. ~~and shall return the funds to the appropriate individuals in accordance with state law.~~

~~f. Change of Ownership. Prior to a change of ownership of a nursing home or boarding care home, a written verification by a public accountant of all patients' and residents' funds shall be provided to the new licensee in exchange for a signed receipt.~~ Post-hearing amendment, accepted by H.E, F # 31 + adopted.

9. ~~(9)~~ Policy Records. All policies and procedures adopted by the home shall be placed on file and be made readily accessible to the personnel.

10. ~~(10)~~ Unusual Occurrences. Any occurrence of food poisoning or reportable disease shall be reported immediately to the Department.

11. ~~(11)~~ Employees' Personnel Records. A current personnel record shall be maintained for each employee and placed on file in a locked cabinet in the office of the administrator, person in charge or the business office. These records shall be available to representatives of the Department and shall contain the following information:

a. ~~(aa)~~ Person's name, address, telephone number, age and birth date, sex, marital status, Minnesota license or registration number, if applicable; name address and telephone number of person to be called in case of emergency; social security number, and similar identifying data.

b. ~~(bb)~~ Resume of individual's training, experience and previous employment; recommendations and references from previous employers.

c. ~~(cc)~~ Dates and results of any pre-employment physical examination and of any subsequent physical examinations.[1]

d. ~~(dd)~~ Date of employment in home, type of position currently held in home; hours of work, attendance and salary records.

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[1] Annual physical examinations are recommended.

e. ~~(ee)~~ The record of all illnesses and accidents.

f. ~~(ff)~~ A listing of all institutes or training courses attended.

g. ~~(gg)~~ At least annual evaluations concerning employee's work performance.

h. ~~(hh)~~ Date of resignation or discharge and reason for leaving.

Amendment to this rule was withdrawn - See E. Finding #38 and Conclusion #4 adopted by Commissioner

7 MCAR § 1.049 ~~HHD 49~~ Medical and dental services.

C. ~~(e)~~ Physicians' examinations and orders.

1. ~~(1)~~ Each patient or resident shall have an admission medical history and complete physical examination performed and recorded by a physician within five (5) days prior to or within 72 hours after admission. The medical record shall include: the report of the admission history and physical examination; the admitting diagnosis and report of subsequent physical examinations; ~~a report of a standard Mantoux tuberculin test or, if the Mantoux test is positive or contraindicated, a chest X-ray within three (3) months in advance of admission and as indicated thereafter;~~ a report of a negative full-sized chest X-ray taken within 45 days prior to admission, if chest X-ray positive, documentation from a physician of freedom from active tuberculosis disease, or documentation from a physician of completion of a preventive tuberculosis therapy; reports of appropriate laboratory examinations; general medical condition including disabilities and limitations; instructions relative to the patient's or resident's total program of care; written orders for all medications with stop dates, treatments, special diets and for extent or restriction of activity; physician's orders and progress notes; and condition on discharge or transfer, or cause of death.

2. ~~(2)~~ Each nursing home patient shall be examined by a physician at least every 6 months and each boarding care home resident at least annually or more often if indicated by the clinical condition. A progress note shall be recorded in the patient's or resident's record at the time of each examination.

3. ~~(3)~~ If orders for the immediate care of a patient or resident are not available at the time of admission, the emergency physician shall write temporary orders which are effective for a maximum of 72 hours.

7 MCAR § 1.052A.1. ~~MHB-52(a)(1)~~ Patient and resident units.

a. ~~(1)~~ A comfortable bed at least 36 inches wide, good springs and a clean, firm comfortable mattress and mattress pad. At least one clean, comfortable pillow with extra pillows available to meet the patient's needs. Clean, light weight blankets and bed linen in good condition and of the proper size shall be kept on hand for use at all times. Clean sheets and pillow cases shall be furnished at least once a week. Each bed shall have a washable bedspread. A moisture-proof mattress cover or rubber or plastic sheeting shall be provided for mattresses of all bed patients and for other beds as necessary. Rollaway type beds, cots, or folding beds ~~or double beds~~ shall not be used.

b. The nursing home and boarding care home shall develop a written policy regarding the use of double beds.

7 MCAR § 1.053 ~~MHD-53~~ Medications.

F. ~~(f)~~ Disposition of medications.

1. If authorized by the attending physician or the physician in charge, medications belonging to patients shall be given to them when discharged or transferred. This shall be recorded on the patient's chart. Unused portions of controlled substances shall be handled by contacting the ~~Bureau-of-Narcotics-and-Dangerous-Drugs.--The-Bureau will-furnish-the-necessary-instructions-and-appropriate-forms,~~ Minnesota Board of Pharmacy who shall furnish the necessary instructions and forms, a copy of which shall be kept on file in the home for two years. Any other unused portions of prescription drugs remaining in the nursing home after the death or discharge of the patient for whom they were prescribed or any prescriptions discontinued permanently, shall be destroyed by the supervising nurse in the nursing home, by flushing them into the sewer system and removing and destroying the labels from the containers~~.~~ or handled in accordance with section F.2., below. A notation of any such destruction giving date, quantity, name of medication and prescription number shall be recorded on the patient's chart. Such destruction shall be witnessed and the notation signed by both persons.

2. Drugs and prescribed medications, other than controlled substances, used in nursing homes may be returned to the dispensing pharmacy in accordance with the provisions of the Minnesota Board of Pharmacy rule, 7 MCAR § 8.032.B.

7 MCAR § 1.055 MHD 55 Dietary service and sanitation.

Post hearing amendment accepted by H.E, F # 42 + adopted

U. ~~(u)~~ Dishwashing. The dishwashing operation shall provide proper separation in the handling of soiled and clean dishes and utensils, and shall conform with either of the following procedures for washing, rinsing, sanitizing and drying. ~~Chemical disinfection is not acceptable~~.

1. ~~(1)~~ Machine washing of dishes and utensils.

a. Hot water sanitizing. The dishwashing machine shall be operated in accordance with the manufacturer's instructions which shall be posted nearby; see MHD 67(cliii). The flow pressure shall be maintained between 15 and 25 pounds per square inch (psi) at the dishwasher. The temperatures of the water shall be maintained at 140°-160°F. for the washing cycle, and at 170°F. for the rinsing and sanitizing cycle, both temperatures measured at tray level. If the same person handles both soiled and clean dishes, he shall wash his hands between operations. Dishes and utensils shall be air dried.

b. Chemical Sanitizing.

(1) Equipment

(a) Dishwashing machines using chemicals for sanitizing shall bear the seal ~~labeling~~ indicating that the machine meets the standards of ~~has been approved by~~ the National Sanitation Foundation. - Post-hearing amendment - accepted by H.E, F # 43 + adopted

(b) Each dishwashing machine shall be equipped with a visual or audible signaling device which indicates when the ~~detergent supply or~~ chemical sanitizing supply is empty. The signaling device shall be maintained in an operating condition.

Post-hearing amendment - accepted by H.E, F # 44 + adopted

Post-hearing amendment - accepted by H.E, F # 45 + adopted

~~(c) The pressure of final rinse water supplies to spray-type dishwashing machines shall not be less than 15 or more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A pressure gauge shall be provided immediately upstream from the final rinse control valve to permit checking the flow pressure of the final rinse water.~~

(c) ~~(d)~~ The clean dish counter shall provide space for at least

4 racks of clean and sanitized dishes and utensils.

(2) Operation

(a) The dishwashing machines shall be operated in accordance with the manufacturer's instructions which shall be posted nearby.

(b) The temperature of the wash water shall not be less than 140°F. (60°C.)

(c) Chemicals added for sanitation purposes shall be automatically dispensed in accordance with the manufacturer's specifications for time and concentration.

(d) The chemical sanitizing rinse water temperature shall not be less than 75°F. (24°C.) nor less than the temperature specified by the chemical manufacturer as indicated on the NSF data plate. - Post-hearing amendment - accepted by HE, F #47 + adopted

(e) All chemical sanitizers used in the dishwashing machines shall bear labeling indicating that the chemical sanitizers are registered by the Environmental Protection Agency and shall contain specific instructions for use.

(f) A test kit or other device that accurately measures the parts per million concentration of the sanitizing solution shall be available and used in accordance with this section.

(i) The concentration level shall be tested in accordance with the manufacturer's instruction each ~~time~~ day the machine is used. - Post hearing amendment - accepted by HE, F #48 + adopted

(ii) The results of the testing shall be recorded in a written log which specifies the result of the test and shall be signed by the individual making the test. The log shall include the name of the chemical used and the manufacturer's recommended concentration of the chemical. This written log shall be maintained for the previous 3 months.

(g) If the same person handles both soiled and clean dishes, he shall wash his hands between operations.

(h) Dishes and utensils shall be air dried.

(i) The dishwashing machine shall be thoroughly cleaned at least once a day in accordance with the manufacturer's recommendation.

2. ~~(2)~~ Hand Washing of Pots and Pans. A three-compartment scullery sink, see MHD 65 (b2aa3), shall be utilized as follows for a complete washing cycle by hand of pots and pans. The first compartment is for soaking and washing, the second compartment is for rinsing, and the third compartment for sanitizing. Sanitizing is accomplished by complete immersion for at least two(2) minutes in 170°F. water. A unit heater capable of maintaining the water in the sanitizing compartment at 170°F. shall be provided, including a long handled wire basket for the removal of the sanitized items. The temperature shall be monitored with a thermometer. If the mechanical dishwasher is used for sanitizing of pots and pans, a sanitizing compartment is not required. Only air drying is permitted.

7 MCAR § 1.057 ~~MHD-57~~ Schedule of fines for uncorrected deficiencies.

(APPLIES TO BOTH NURSING HOMES AND BOARDING CARE HOMES)

A. ~~(a)~~ A $50 penalty assessment will be issued under the provisions of Minn. Stat. § 144.653, subd. 6 (1974) for non-compliance with correction orders relating to the sections of these regulations listed below.

MHD 44 (o); (p); (q); (s); (t); (u)

MHD 45 (a)(3); (f); (h)(1); (h)(2)(aa); (h)(2)(ff); (h)(4)

MHD 46 (a); (b); (j); (k)

MHD 47 (c); (e)

MHD 48 (a)(4); (a)(5); (a)(6); (a)(7); (a)(9); (a)(11)

MHD 50 (a); (j)

MHD 52 (a)(2); (a)(3); (a)(4); (a)(9); (d); (e)

MHD 54 (a)(7); (b)(5)

MHD 55 (i)

MHD 56 (f); (h)

MHD 64 (a)(22); (b)(15)

B. ~~(b)~~ A $250 penalty assessment will be issued under the provisions of Minn. Stat. § 144.653, subd. 6 (1974) for non-compliance with correction orders relating to all other sections of these regulations not specifically enumerated in section ~~(a)~~ A. ~~above.~~ or C.

C. Nursing Homes

1. A $50 penalty assessment will be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.048 A.4.

b. 7 MCAR § 1.048 A.8.a.

c. 7 MCAR § 1.048 A.8.b.(2)

d. 7 MCAR § 1.048 A.8.c.(3)

e. 7 MCAR § 1.048 A.8.c.(5)

f. 7 MCAR § 1.048 A.8.c.(6)

g. 7 MCAR § 1.048 A.8.d.

h. 7 MCAR § 1.048 A.8.e.

i. 7 MCAR § I.048 A.8.f.

j. 7 MCAR § 1.052 A.1.b.

k. 7 MCAR § 1.053 F.2.

l. 7 MCAR § 1.055 U.1.b.(1)(d)

m. 7 MCAR § 1.064 A.3.f.(1)(a)

2. A $150 penalty assessment will be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.046 L.2.b.

b. 7 MCAR § 1.046 L.2.c.

c. 7 MCAR § 1.046 L.2.d.

d. 7 MCAR § 1.046 L.2.e.

e. 7 MCAR § 1.046 L.2.f.

p 7 MCAR § 1.046 L.3 - hearing amendment, accepted by H.E., F#59, renumbering - Commissioner's Finding #35

g ~~f.~~ 7 MCAR § 1.047 A.

h. ~~g.~~ 7 MCAR § 1.048 A.8.b.(1)

i ~~h.~~ 7 MCAR § 1.048 A.8.c.(1)

j ~~i.~~ 7 MCAR § 1.048 A.8.c.(2)

k ~~j.~~ 7 MCAR § 1.048 A.8.c.(4)(a)

l. ~~k.~~ 7 MCAR § 1.048 A.8.c.(4)(b)

m ~~l.~~ 7 MCAR § 1.048 A.8.c.(4)(c)

n ~~m.~~ 7 MCAR § 1.048 A.8.c.(7)

o ~~n.~~ 7 MCAR § 1.055 U.1.b.(1)(a)

p ~~o.~~ 7 MCAR § 1.055 U.1.b.(1)(b)

q ~~p.~~ 7 MCAR § 1.055 U.1.b.(1)(c)

s ~~r.~~ 7 MCAR § 1.055 U.1.b.(2)(b)

t ~~s.~~ 7 MCAR § 1.055 U.1.b.(2)(c)

u ~~t.~~ 7 MCAR § 1.055 U.1.b.(2)(d)

v ~~u.~~ 7 MCAR § 1.055 U.1.b.(2)(e)

w ~~v.~~ 7 MCAR § 1.055 U.1.b.(2)(f)

x ~~w.~~ 7 MCAR § 1.055 U.1.b.(2)(g)

y ~~x.~~ 7 MCAR § 1.055 U.1.b.(2)(h)

z ~~y.~~ 7 MCAR § 1.055 U.1.b.(2)(i)

3. A $250 penalty assessment shall be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.046 L.2.a.

~~b. 7 MCAR § 1.049 C.1.~~

b ~~a.~~ 7 MCAR § 1.064 A.3.f.(1)(b)

Deleted since amendment to this rule was withdrawn - See Commissioner's ~~Findings~~ Conclusions #. as amended. ~~by the Amended~~

7 MCAR § 1.058 Allowable time periods for correction.

A. Allowable time periods for correction. The allowable time periods for complying with a correction order issued by the Department shall be as follows:

1. 7 MCAR § 1.046	
a. L.2.a.	30 days
b. L.2.b.	14 days
c. L.2.c.	14 days
d. L.2.d.	14 days
e. L.2.e.	14 days
f. L.2.f.	14 days
g. L.3	30 days
2. 7 MCAR § 1.047A	14 days
3. 7 MCAR § 1.048	
a. A.4.	14 days
b. A.8.a.	30 days
c. A.8.b.	14 days
d. A.8.c.(1)	30 days
e. A.8.c.(2)	30 days
f. A.8.c.(3)	30 days
g. A.8.c.(4)(a)	14 days
h. A.8.c.(4)(b)	30 days
i. A.8.c.(4)(c)	30 days
j. A.8.c.(5)	30 days
k. A.8.c.(6)	30 days
l. A.8.c.(7)	14 days
m. A.8.d.	14 days
n. A.8.e.	14 days
o. A.8.f.	30 days

Hearing amendment, accepted by H.E., F # 62 & adopted

~~4. 7 MCAR § 1.049C.1.~~		~~14 days~~
4 ~~5.~~ 7 MCAR § 1.052A.1.b.		30 days
5. ~~6.~~ 7 MCAR § 1.053F.2.		30 days
6. ~~7.~~ 7 MCAR § 1.055		
a. U.1.b.(1)(a)		60 days
b. U.1.b.(1)(b)		30 days
c. U.1.b.(1)(c)		~~14~~ 30 days
d. U.1.b.(1)(d)		60 days
e. U.1.b.(2)(a)		14 days
f. U.1.b.(2)(b)		14 days
g. U.1.b.(2)(c)		14 days
h. U.1.b.(2)(d)		14 days
i. U.1.b.(2)(e)		14 days
j. U.1.b.(2)(f)		14 days
k. U.1.b.(2)(g)		14 days
l. U.1.b.(2)(h)		14 days
m. U.1.b.(2)(i)		14 days
7. ~~8.~~ 7 MCAR § 1.064		
a. A.3.f.(1)(a)		30 days
b. A.3.f.(1)(b)		14 days

Deleted since the amendment to the rule was withdrawn - See conclusion n. of the Commissioner as amended

hearing amendment, accepted by HE, F # 62 and adopted

B. Extension of the allowable time period for correction. - Post hearing amendment - accepted by HE, F # 65 and adopted

1. Request for extension. The ~~administrator of the~~ nursing home may request an extension of the allowable time for correction for those rules specified in section A., above. The request for extension of the allowable period of time for correction shall be received by the Department prior to the expiration of the time period cited in the correction order. The failure to submit a request within that time period shall result in a denial of the request.

2. Contents of request.

a. All requests for an extension of the allowable time period for correction shall contain the following information:

(1) The identification of the rule or rules for which the correction order was issued;

(2) The date the correction order was received;

(3) The allowable time period for correction;

(4) The reasons for requesting an extension of the allowable time period for correction which shall specify, in detail, the steps that have been taken by the nursing home to attain compliance;

(5) The length of additional time required to attain compliance with the correction order; and

requested by HF, F #52 & C #3 adopted by Commissioner

(6) Such other relevant information ~~which the Department shall determine is~~ necessary to evaluate the request for the extension of time.

b. If the request for an extension is made orally, the administrator shall mail, within ~~24 hours~~ one business day - Commissioner Finding #37, a written confirmation which contains the information specified under section 2.a., above.

3. Criteria for evaluation.

a. A request for an extension of the allowable period of time shall be granted if the Department determines that:

(1) Continued non-compliance with the rule for the length of the extension will not jeopardize the health, treatment, comfort, safety or well-being of the patients; and

(2) The nursing home:

(a) Has entered into a contract to obtain the materials, labor, personnel, or other items necessary to obtain compliance with the correction order, but the supplies, - Hearing amendment, accepted by H.E, F #62 adopted contractor or individual has failed to perform or is unable to perform within the time period specified and the inability of the nursing home to

comply with the correction order is due solely to that failure; or

(b) Has otherwise made a diligent good faith effort to comply with the correction order since its receipt.

b. The administrator shall be notified, in writing, of the Department's decision. If an extension of time is granted, the notification shall specify the additional time allowed for correction.

4. Renewal.

a. Any request for the renewal of an extension of the allowable time period for correction shall be made in accordance with section B.1. and 2., above.

b. Approval for the renewal of an extension of the allowable time period for correction shall be granted if the Department determines that the nursing home continues to meet the criteria contained in section B.3., above.

5. Denial. The Department shall deny any request for an extension of the allowable time period for correction if it determines that the criteria specified in section B.3., above, are not met. The denial shall be in writing and shall list the reasons for the denial.

7 MCAR § 1.064 A.3.f. ~~MHD-64(a)(3)(ff)~~ Bedroom doors.

(1) ~~(ff1)~~ Existing and new. ~~There shall be no locks on patient room doors.~~

(a) The nursing home shall develop a written policy regarding the use of locks on patient bedroom doors. The policy shall address whether or not doors can be locked while the patient is in the room.

(b) ~~Any locks installed on patient bedroom doors shall be so arranged that they can be locked only from the corridor side~~. All such locks shall permit exit from the room by a simple operation without the use of a key. All locks shall be openable with a master key which is located at each nursing station.

Commissioner's Finding 24 & amended conclusions of the Commissioner

MINNESOTA ASSOCIATION OF HEALTH CARE FACILITIES

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MINNEAPOLIS, MINNESOTA 55420

TELEPHONE: 612/854-2844

April 21, 1980

Mr. George A. Beck
Office of Hearing Examiners
1745 University Avenue
St. Paul, Minnesota 55104

Re: In the Matter of Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes.

Dear Mr. Beck,

The Minnesota Association of Health Care Facilities wishes to submit written comments on the above-referenced subject matter as a follow-up to comments made at the public hearing conducted on April 1 and 2, 1980.

Our comments herein will, in some instances, contain suggested alternative or additional language for a particular rule. In such cases we have attached a separate sheet indicating the deletions and additions we suggest. In addition, we have attached hereto supplementary documents which we would like to have entered in the record as public exhibits. For your convenience, our comments herein will be divided by subject matter as was done at the public hearing.

GENERAL COMMENTS

We would like to comment initially on the Department's Statement of Need and Reasonableness, and the Statement of Anticipated Costs and Benefits. Both of these documents suffer from lack of specificity and appear not to comply with the requirements of statute and rule.

Minnesota Statutes §15.0412, Subd. 4 requires that

"At the public hearing the agency shall make an affirmative presentation of facts establishing the need for and reasonableness of the rule

proposed for adoption . . . " (emphasis supplied)

At the hearing on April 1 and 2 the Department stated that the Statement of Need and Reasonableness contained all of the evidence that the Department would present (see Transcript p. 12-13). The Department's oral statement at the hearing merely summarized what was in the Statement of Need and Reasonableness.

The requirements of the statute are amplified in 9 MCAR §2.104. This rule provides, inter alia, that

> "The Statement shall be prepared with sufficient specificity so that interested persons will be able to fully prepare any testimony or evidence in favor of or in opposition to the rule/rules proposed."

In many cases (which we will point out in our comments on specific rules below) the Statement of Need does not satisfy these requirements. The Statement does not, in all cases, contain facts which support the reasonableness of a proposed rule, but rather contains only a general statement that the proposed rule "is reasonable". Further, as became clear during the hearing, there were many crucial issues and questions which were not clarified in the Statement and which were not answered at the hearing. The answers to these questions, as we pointed out at the hearing, have an important bearing on the reasonableness of the proposed rules.

The Statement of Anticipated Costs and Benefits is defective and incomplete. There are three separate provisions of state law which require the preparation of a cost statement for these rules. First, Minnesota Statute §144A.29, Subd. 4, requires

> "Each rule promulgated by the commissioner of health pursuant to sections 144A.01 to 144A.17 shall contain a short statement of the anticipated costs and benefits to be derived from the provisions of the rule."

The Department has taken the position that certain specific rules will not have a cost impact at all, e.g. the rules on variances/waivers, schedule of fines, and schedule of allowable time periods for correction. This is demonstrably incorrect, as we will point out in our comments below on specific rules.

The Department has also taken the position that certain rules are not mandatory, and therefore the Department is unable to estimate the costs associated with it, e.g. the rules on handling of funds, handling of oxygen. This does not satisfy the requirements of the statute. The fact that it may be difficult to estimate the costs does not mean that the Department does not have to attempt to do so. The fallacy in the Department's position is demonstrated by the rule on handling patient funds. Although the rule does not require the handling of funds, it does impose definite requirements for facilities that do handle such funds (as do most facilities in the state). Clearly, therefore, there are costs associated with this rule.

The second statutory requirement for estimating costs is contained in Minnesota Statutes §15.0412, Subd. 7 which states

> "If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, the notice of the proposed rule as required by this section shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local bodies in the state to implement the rule for the two years immediately following adoption of the rule if the estimated total cost exceeds $100,000 in either of the two years. For purposes of this section, local public bodies shall mean officers and governing bodies of the political subdivisions of the state and other officers and bodies of less than state wide jurisdiction which have the authority to levy taxes."

Under the formula applied in Minnesota for the Medical Assistance program, Minnesota counties pay 4.43% of all medical assistance costs. The result of the application of this formula yields the fact that a total expenditure for the 438 nursing homes in the state, of $2,256,336 will cause the required $100,000 to be exceeded. In other words, if the average cost of these rules to each nursing home is only slightly over $5,000 annually, then the above-quoted subdivision applies. We believe it is self-evident that these rules will cause at least that great of an expenditure. The Department's notice did not include the required estimate, and therefore did not comply with the statute.

Finally, the cost of proposed rules is required to

be estimated and supplied to the House Appropriations and Senate Finance Committees, if the cost is in excess of $100,000, pursuant to Laws 1979, c. 336 §15 [codified as Minnesota Statute §15.065]. Again, the Department has not complied with this mandate.

7 MCAR §1.048.A.8. Records and Reports

As we indicated at the public hearing on April 1, the Minnesota Association of Health Care Facilities suggests that the rule regarding the handling of patient funds be withdrawn at this time. As several of the people who testified at the hearing indicated, there are pending developments in this area both at the federal level and at the state level. The Federal government is in the process of drafting regulations governing the handling of patient funds, and the legislature this session passed a bill that provides additional guidelines in the handling of patient funds. We have attached a copy of the bill to these comments. In an area as sensitive and complex as the handling of patient funds, it makes particular sense to have the federal and state rules be consistent with one another. We think that the Department would be well advised to withdraw these rules at this time in order to give the Department time to analyze these federal and state developments to gauge their impact on the rules that have been proposed. Such an action would be consistent with the concern voiced by the Legislative Commission to Review Administrative Rules, that nursing homes not be subject to duplicative and inconsistent regulations if that can be avoided. We have attached a copy of the LCRAR staff report which highlights this concern.

Several of the consumer groups that were represented at the hearing spoke in favor of requiring the nursing home to handle patient funds if requested to do so. We would like to reiterate our comments made at the time of the hearing that we think it is inappropriate for the Department to mandate that at this time, and we support the Department's position in the proposed rule. We think that the Department is not authorized by statute to make that kind of a rule mandatory, and should proceed with great caution in imposing a fiduciary relationship on a nursing home. In addition, nursing homes may not have the financial or accounting capabilities to adequately handle patient funds. By our comments we do not mean to imply that the Minnesota Association of Health Care Facilities is opposed to facilities handling patient funds on behalf of their residents. In fact, we believe that facilities that do handle patient funds

provide a valuable and important service to their residents. We certainly do not think that its inappropriate for a facility to voluntarily assume responsibility for handling the funds of its residents. On the other hand, we don't think it is appropriate for the state to mandate the handling of those funds in cases where the facility feels that that would put them in a difficult position.

Comments on Specific Rule Provisions

Re: A.8.c. (4) (a) - This proposed rule requires the facility to assure that access to records relating to residents' funds be allowed "at least one hour, five days per week". We believe that this provision may be applied in a manner that would disrupt the normal functioning of the facility. Allowing residents access to information regarding their balance at least one hour, five days per week would probably not create a problem. However, allowing access to all resident funds records, including itemized transactions, receipts, etc. could create a problem if mandated daily. We would hope the Department would address this problem in the final rule.

Re: A.8.c. (4) (c) (iii) - This proposed rule requires that the facility obtain receipts from the resident's family, guardian or friend when the resident has designated another person to make purchases for the resident. We think it is important that it be clearly understood that the facility has no way of complying with this requirement. If the family member, for example, does not give a receipt to the facility, there is nothing that the facility can do to require the family member to in fact produce the receipt. We would refer the Hearing Examiner and the Department to the provisions of the bill which we mentioned earlier, HF 729/SF 750 which did pass the legislature. The provisions of this bill make the misuse of resident's funds "theft" and requires persons to document that purchases for the resident were actually made with the money received. If the Department rejects our suggestion that the entire rule be withdrawn, certainly this rule should be amended to make it consistent with the statute and to remove the burden from the facility for obtaining those receipts.

Re: A.8.c. (6) - This provision would require that, if personal funds are deposited in an interest-bearing accout, the accrued interest must be prorated. Although this provision seems fair, as a practical matter it is a great deterrent to placing those funds in an interest-bearing account because of the tremendous difficulties in prorating the interest. In many cases, there may be hundreds of transactions per week in residents' funds accounts. Health care facilities do not have the same

access to computers or other sophisticated accounting practices that would allow them to efficiently prorate the interest. We think that the Department should reconsider mandating that interest be prorated. We would also point out that this provision is not consistent with the latest draft of the proposed federal regulations having to do with the handling of patient funds.

Re: A.8.e. - We would suggest that on page 13 of the document that was mailed out, everything after the word, "funds" be deleted. This language is unnecessary, since a facility is required by law to return the funds to the appropriate person in any case. We would point out, however, that it is frequently difficult for the facility to ascertain exactly who the appropriate person is.

7 MCAR §1.046 L. Use of Oxygen

No additional comments.

7 MCAR §1.047.A. and 1.049.c.

We would like to reiterate the comments made at the hearing regarding the difficulty of getting doctors, and patients to comply with this. Any rule which subjects a facility to a correction order and fine for the failure of another health professional, or a patient, is unreasonable. We believe that if a physician fails to supply documentation, or if a patient chooses not to have an x-ray (as is his or her right under the Patients' Bill of Rights), the facility should not be cited. In Amendment Number One, we have suggested language that would make it clear that a good faith effort to comply is all that is required.

7 MCAR §1.048.A.4. Retention of Records

We support the proposed amendment.

7 MCAR §1.052.A.1.b. Double Beds

We support the proposed amendment.

7 MCAR §1.053.F. Medications

No comment.

7 MCAR §1.055.U. Dietary Service and Sanitation

We support the proposed amendment. We would suggest a technical amendment that would clarify that the two dishwashing procedures are in the alternative, See Amendment Number Two.

7 MCAR §1.064 A.3.f. Bedroom Doors

No additional comments.

7 MCAR §1.044.X. Variance and Waiver

The Minnesota Association of Health Care Facilities strongly supports the concept of allowing waivers and variances, and strongly supports clearly delieneating the procedures and criteria for granting waivers and variances. Nursing home licensure rules are extensive and complex, and there is a clear need to have some flexibility in their application to individual circumstances.

At the hearing we asked the question of whether or not the Department might take the position that a request for a variance or waiver is somehow an admission of being in violation of a particular rule. The Department would not give a specific response to this although Mr. Breviu indicated (T. 151) that

> "it would probably depend upon the facts that we're presented with and the hypothetical case that you have in mind and I think it may be difficult to state definitively one way or the other at this time . . ."

We believe it is important to clarify this. It would be extremely unfair to put a facility in the position of asking for a waiver/variance and then being fined as being in violation because they were deemed to have admitted the violation. We are proposing specific language to make it clear that the request for a waiver/variance is not an admisison of being in violation (see Amendment Number Three).

Another general question which we raised at the hearing related to whether a request for a waiver/variance will operate to stay the accrual of a fine while the request is being processed by the Department. Mr. Breviu indicated (T. 153) that the Department would not take the position that a request for a waiver/variance would operate to stay

the accrual of a fine. We are suggesting language (see Amendment Number Four) which would make it clear that such a request would stay the accrual of any fine. It seems only fair that this be the procedure, otherwise a facility might be forced to forego requesting a waiver/variance, even in a legitimate case, because the facility is faced with a possibily ruinous fine while the request is being processed. We are suggesting additional language (see below) that would require the Department to make a decision on a waiver request within 30 days of receipt, and with this additional language such a temporary stay of the accrual of a fine is reasonable. In fact, without some time limitation on the Department, a request for a waiver/variance could be ignored by the Department and the facility would be forced to comply because of the prospect of enormous fines running indefinitely. We think that it is necessary and reasonable that the language in Amendment Number Four be added to the rule.

Re: X.2.d. - In response to our question, Mr. Tripple (T. 154) indicated that a waiver/variance could be granted on a permanent basis. We agree with this. There may be a variety of circumstances where a permanent waiver/variance is reasonable. We would suggest that the Department give some thought to proposing specific criteria that would be utilized.

Re: X.3.a.(1) - We would suggest that this criteria be deleted. It is both misleading and unnecessary. The Statement of Need and Reasonableness at page 7 states that "The Department realizes that in some situations, alternative measures would not be feasible. In these situations, the facility would simply specify that alternative measures would not be possible and explain why." And further at page 8 the Statement of Need and Reasonableness states, "In situations where alternative measures would not be available, the Department would note this fact during their review." The criteria is misleading because X.3.a.(1) states that a variance or waiver shall be granted if the Department determines that each one of the criteria are met, and then goes on in the next page under X.6. to say that a waiver shall be denied if an applicant cannot meet all three criteria and yet the Department has admitted that at least one of the criteria may not be able to be satisfied even in a legitimate case where the Department might grant a waiver.

The criterion is unnecessary because again as the Department states further on in the Statement, "The second criteria parallels, to a certain extent, the provisions of the first criteria." "In many situations, the review of the alternative measures will also be intertwined with the determination of the adverse effect of the

variance or waiver." And as we see it the terms "equivalent or superior to" only have meanings in relation to their effect upon the health and treatment, comfort and safety and well-being of the resident and that criterion is already in subparagraph (2).

The additional language suggested at the hearing by Mr. Breviu (T. 156 lines 7-9) would be a substantial improvement in the rule, however we believe a better alternative is to delete subparagraph (1) entirely (See Amendment Number Five).

Re: X.4. - We would reiterate our comments made at the hearing that there may be situations in which it is unreasonable to automatically apply to the alternative measure the same period of time for correction and amount of fines as those for the particular rule which is being waived. There may be cases where the alternative measures necessitate action that is different in scope or different in nature than the actions that might be taken to comply with the literal requirements of the rule. The criteria that the Department used in proposing a 14 day, 30 day, or 60 day time period for compliance with particular rules might suggest a different time period for certain alternative measures. We are proposing specific language in Amendment Number Six to solve this problem.

Re: X.5.a. - We believe that requiring requests for a renewal of a waiver/variance to be submitted prior to the expiration date is unnecessary and unreasonable. It may lead to the routine request for renewals which are not necessary, as a way for facilities to "cover" themselves against some unforeseen, last-minute problem. We are suggesting deleting this part of X.5.a. (see Amendment Number Seven).

Re: X.6. - This paragraph does not contain any requirement that the Department issue a decision within any specific period of time, nor does it require that the Department specify the reasons for its action. As we stated at the hearing, we believe a better procedure is one contained in Draft 4, General Provisions-Revised Rules, dated June, 1979, which was approved by the Nursing Home Advisory Council. We have suggested such language in Amendment Number Eight. The statement of reasons is necessary to enable the facility to make an intelligent decision on whether to appeal or not. The 30-day time period is necessary so that a facility is not left hanging indefinitely, so that the facility may make any necessary arrangements to comply with the rule if that is the decision.

The 30-day time period will be particularly necessary if the Department rejects our suggestion that the request for a waiver/variance stay the accrual of any fine. If there is no stay of the accrual of a fine and there is no time limit on the Department for making a decision, obvioulsy very few facilities would be willing to run the risk, and the entire waiver/variance rule would be unworkable and impractical for facilities.

7 MCAR §1.057 Schedule of Fines

Our comments on this proposed rule will be lengthy, however these provisions are of absolutely crucial importance to nursing homes in Minnesota and we hope the hearing examiner will carefully consider the issues we raise. Furthermore, they are crucial to the fair and equitable operation of the entire nursing home licensure system. As we pointed out at the hearing, many important questions remain unanswered, and we hope that the hearing examiner's recommendations will address these unanswered questions.

One critical issue relates to whether or not the Department will accrue the fines on a daily basis even when an appeal has been taken from an assessment. At the hearing the Department refused to answer this question (T. 182-183), and yet the issues is important not only in itself, but it also affects the reasonableness of other provisions such as the amount of daily fines, the allowable time periods for correction, the operation of the waiver system, and others. The statute is almost four years old and the Department certainly must have considered this issue. We believe that, whatever the policy is, it should be clearly spelled out in the rule to give nursing homes reasonable notice of how the system will work.

The Department indicated, in response to our question, that this was a question of statutory interpretation and therefore is not relevant to the adoption of the proposed rules (T. 181). We agree that it is a matter of statutory interpretation, but strongly disagree that it is not relevant. As we pointed out above, this question affects any decision regarding the reasonableness of other rules. Also, we believe that whatever the Department's position is on the question of accrual of fines during an appeal, it is and should be a rule. Minn. Stat. §15.0411, Subd. 3 states

> "'Rule' includes every agency statement of general applicability and future effect, including the amendment, suspension, or repeal thereof, made to implement or make specific the law enforced or

> administered by it or to govern its organization or procedure . . . "

In establishing a policy on this question, the Department is promulgating a rule, and that rule should be tested by the processes outlined in the Administrative Procedures Act just as are the other rules.

The Minnesota Association of Health Care Facilities believes that §144A.10, on which the Department is relying in promulgating a schedule of fines, does not mandate the daily accrual of fines when a good faith appeal has been filed. Understanding the meaning of §144A.10 is complicated by the lack of definitions for some very important terms. Two of the more important undefined terms are "violation" and "noncompliance". Both of these terms are used in §144A.10 in respect to correction orders. They are, in effect, legal conclusions. Once a facility is found to be in "violation", or in "noncompliance", then certain results follow under the statute. The important question, however, is: When, and under what circumstances, is a facility in "violation" or in "noncompliance"? The answer should be that a facility falls into those categories when one of two situations exist; either (1) the facility was issued an assessment and did not appeal it, in which case the allegation in the assessment is conceded to be true, or (2) the facility appealed from an assessment and lost the appeal. The third possible situation is where a facility receives an assessment and then appeals from the assessment. In such a situation the allegation in the assessment is immediately placed in doubt, as a legal matter. Once a facility has filed an appeal, the Department bears the burden of proving, by a preponderance of the evidence, that the facility is in "violation" or "noncompliance", see 9 MCAR §2.217.c.5. Therefore, it cannot be said that a facility that has appealed from an assessment is, in fact, in "violation" or "noncompliance". To do so would be inconsistent with the Administrative Procedures Act and the rules promulgated pursuant thereto, and would, we believe, be a denial of due process as well.

It is in this framework, then, that we can look at the language of subdivision 5, 6, 7 and 8 of §144A.10. Subdivision 5 provides:

> Subd. 5. Reinspections. A nursing home issued a correction order under this section shall be reinspected at the end of the period allowed for correction. The reinspection may be made in conjunction with the next annual inspection or any other scheduled inspection. If upon

> reinspection the representative of the commissioner of health determines that the facility has not corrected a violation identified in the correction order, a notice of noncompliance by certified mail to the nursing home. The notice shall specify the violations not corrected and the fines assessed in accordance with subdivision 6. (emphasis added)

Again, a facility may only be said to be in "violation" or "noncompliance" if it has either not appealed the assessment, or has appealed and lost. If the facility has an appeal pending then the allegations in the assessment are in doubt, and the facility is only in violation or or noncompliance after the Department has proven it by a preponderance of the evidence.

Subdivision 6 is the most important in understanding the statute. It provides:

> Subd. 6. Fines. 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 promulgated by rule of the commissioner of health. 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 $250 per day of noncompliance. (emphasis supplied)

As the underlined sentence makes clear, for a facility to be assessed a daily fine, two criteria must be met: (1) the facility must be in "noncompliance" and (2) the facility must have failed to give a notice of correction. As pointed out above, if the facility has appealed from a correction order, it cannot be said to be in noncompliance while the appeal is pending because the whole point of the appeal is to determine that question.

The Department, in a meeting on March 19, indicated the belief that subdivisions 7 and 8 supported an interpretation that §144A.10 mandated daily accrual of fines even during an appeal. We do not believe that is true if the appropriate meanings are given to the terms "violation" and "noncompliance" as outlined above. Subdivision 7 deals

with the accumulation of fines and subdivision 8 deals with the recovery of assessed fines. Both of these subdivisions are based on the presumption that a valid fine has been or is being assessed pursuant to subdivision 6. Under the construction that we urge, no valid fine may be assessed under subdivision 6 when an appeal has been filed, and therefore subdivisions 7 and 8 do not support the daily accrual of fines during an appeal.

We believe that the interpretation of §144A.10 outlined above is a reasonable and appropriate one, one that does not saddle the Department with an unworkable and unfair tagging system, and one that meets the requirements of due process.

If the Department's apparent intention to accrue fines on a daily basis even during a good faith appeal is implemented, not only will the system be unreasonable, unfair and unworkable, it will also be unconstitutional. An understanding of how this new system would operate is essential to understanding its constitutional defects. Under this new system, a nursing home might be inspected by the regular surveyors (or the Office of Health Facility Complaints) and might be issued a correction order for the violation of a rule. The correction order would be based on the surveyor's observations and on his or her interpretations of the rule and of the facts of the situation. The nursing home would be given a specific period of time in which to correct the alleged deficiency (e.g. 30 days). At this point, under current Department policy, the facility cannot appeal the correction order (see our comments on 7 MCAR §1.058 below), even if the correction order is totally in error. On Day 30, the facility will be issued an assessment if, according to the surveyor, the alleged deficiency has not been corrected, and the fine begins accruing. Only then may the facility appeal, once the fine has already begun accruing. Obviously, at $50, $150, or $250 a day, very few facilities will want to risk filing an appeal, no matter how meritous.

When this system is analyzed in light of basic constitutional principles, it is clearly unconstitutional. The basic principles of due process of law require that an individual be afforded the opportunity to be heard before a penalty or fine is assessed against that individual. Furthermore, no penalty can be of such a nature so as to effectively deprive an individual of the right to be heard. The general rule may be stated as follows:

> "Where penalties prescribed for a violation of a statute or of a state constitution are of so extreme a character as probably to prevent resort to the courts to test the validity of

> a statute or the constitution, there is a lack of due process of law; and a statute which provides such penalties for non-compliance with an administrative order or regulation must afford reasonable opportunity to test the validity of the order or regulation in the courts." 16 Am. Jur. 2d Constitutional Law, §640.

Basic constitutional guarantees of due process and the right to petition for a redress of grievances are found in both the United States and Minnesota constitutions. The Fourteenth Amendment to the United States Constitution, applicable to the states and subdivisions thereof, provides that:

> "No State shall make or enforce any law which shall abridge the privileges of immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."

Art. 1, §7 of the Minnesota Constitution (Restructured-1974) also guarantees due process of law to the citizens of the State of Minnesota. As is guaranteed under the First Amendment to the United States Constitution, the State of Minnesota has guaranteed to its citizens the right to redress of grievances. In Art. 1, §8 of the Minnesota Constitution (Restructured-1974):

> "Every person is entitled to a certain remedy in the laws for all injuries or wrongs which he may receive to his person, property or character, and to obtain justice freely and without purchase, completely and without denial, promptly and without delay, conformable to the laws."

The penalty system provided under the system envisioned by the Department effectively denies an individual or nursing home or boarding care facility the opportunity to contest a fine because of the prohibitive effect of a cumulative fine. Given the present backlog in the courts of the State of Minnesota and delays incurred through the Office of Hearing Examiners, it is conceivable that a final determination would not be obtained for a number of years, during which time a fine would continue to accrue. A $250 fine accrued over one year, for example, would amount to over $90,000. With this kind of threat

it is difficult to see how any facility would challenge any fine, no matter how unjust. And it is indisputable that many fines in the past have been improperly imposed.

One of the leading cases striking down a lesser peanlty system similar to the scheme found in Section 10 is Oklahoma Operating Co. v. Love, 252 U.S. 331, 40 S. Ct. 338, 64 L. Ed. 596 (1920). An order of the Oklahoma Corporation Commission prohibited plaintiff therein from raising its rates on the ground that the laundry business conducted by pleaintiff was in the nature of a public business, and thus the rates charged were subject to approval by the Commission. Plaintiff operated under this scheme for a few years, but then raised its rates without approval of the Commission. As a result of its actions, plaintiff became subject to comtempt proceedings. Furthermore, plaintiff was subject to a $500 per day fine for its failure or refusal to obey an order of the Commission.

The original order of the Commission declaring plaintiff a public business was made after notice and hearing, as was the order assessing the daily fine. As an aside, no hearing would be provided under the Department's system before a fine is assessed and begins to accrue. Although the order originally declaring plaintiff a public business was subject to appeal directly to the Oklahoma Supreme Court, rate orders could not be so appealed. The rate could be appealed or contested only in conjunction with a contempt proceeding for failure to comply with the rate order. An appeal to the Supreme Court was conditioned upon the filing of a surety bond in double the amount of the fine assessed, with the bond suspending the fine.

The Oklahoma scheme was struck down forcefully by the United States Court as being in violation of due process of the law. The Court stated that the limited method of appeal, coupled with the daily fines, effectively deprived plaintiff of its right to be heard:

> "But the penalties, which may possibly be imposed, if he pursues this course without success, are such as might well deter even the boldest and most confident . . . . Obviously a judicial review beset by such deterrents does not satisfy the constitutional requirements, even if otherwise adequate, and therefore the provisions of the acts relating to the enforcement of the rates by penalties are unconstitutional without regard to the question of the sufficiency of those rates." 252 U.S. at 336-337.

A similar decision on an analogous situation made on the same day is Oklahoma Gin Co. v. State of Oklahoma, 252 U.S. 339, 40 S.Ct. 341, 64 L.Ed. 600 (1920).

The scheme the Department apparently intends to implement is more onerous than that found in the above Oklahoma cases. At least in the Oklahoma cases, the original orders declaring a business to be a public business were issued following notice and hearing. The initial order was immediately appealable, although the rate-setting orders of the Commission were not. In the case at hand, correction orders and notices of non-compliance, giving rise to fines, are issued merely upon the determination of an employee of the Health Department to do so. There is no opportunity for a hearing until after the daily fine begins to accrue. The Minnesota scheme is more violative of due process than the scheme at issue in the Oklahoma cases.

A 1971 Ninth Circuit decision struck down a penalty system under which fines of up to $1000 per day per violation could be assessed. In United States v. Pacific Coast European Conference, 451 F.2d 712 (CA 9 1971), the Court had occasion to review a 1961 act which prohibited, for the most part, a dual rate contract system used in international shipping. Defendants challenged the uniform contract that was required, if not in form then at least in substance, by the Federal Maritime Commission. The Commission attempted to assess fines against the defendants for periods extending from April 4, 1964, through December 31, 1966, at which time defendants came into compliance with the statute.

The District Court granted summary judgment for defendants on the issue of the penalty. Defendants based their motions for summary relief on:

> "'the constitutional principle, established by a long line of Supreme Court cases, that statutory penalties cannot lawfully attach during the period of a bona fide judicial review of a legislative act, whether statute or administrative agency ruling.'" 451 F.2d at 715-716.

Although the District Court did not state its basis in arriving at the ruling favorable to defendants, the Appellate Court assumed that it was on the grounds urged by defendants.

In its discussion upholding the action of the District Court, the Ninth Circuit examined the "tolling doctrine"

and its purposes. The Court cited a 1915 United States Supreme Court case, Wadley v. Southern Railway Company v. Georgia, 235 U.S. 651, 35 S.Ct. 214, 59 L.Ed. 405 (1915), in which a $5000 per day statutory penalty was declared invalid. The Ninth Circuit decision quotes extensively from Wadley, and it is appropriate to here restate part of the Wadley opinion:

> "A statute therefore which imposes heavy penalties for violation of commands of an unascertained quality, is in is nature, somewhat akin to an ex post facto law since it punishes for an act done when the legality of the command has not been authoritatively determined. Liability to a penalty for violation of such orders, before their validity has been determined, would put the party affected in a position where he himself must at his own risk pass upon the question. He must either obey what may finally be held to be a void order, or disobey what may ultimately be held to be a lawful order. If a statute could constitutionally impose heavy penalties for violation of commands of such disputable and uncertain legality the result inevitably would be that the carrier would yield to void orders, rather than risk the enormous cumulative or confiscatory punishment that might be imposed if they should thereafter be declared to be valid." 235 U.S. at 662-663.

The Court was, of course, concerned with frivolous attacks on statutes or administrative rules in an attempt to evade the assessed penalty. The Court stated that even though a statute or order is upheld on review, such does not make an appeal frivolous and thus cause the reimposition of the penalty. The right to test the validity of a statute or administrative order is to be judged, not by an after-the-fact determiniation, "but by whether defendants mounted a substantial attack upon the validity of the statute and order." 451 F.2d at 719. The Wadley Court went on to state that even partial impairment of "judicial review protected by the tolling doctrine" [i.e. tolling of assessment during review] is "impermissible" 451 F.2d at 719. Clearly the system envisioned by the Department will substantially impair the right to judicial review by making such review extremely and unreasonably costly.

The Wadley case cited above also traces through pre-1914 federal and state court decisions in which penalty

schemes were found to deprive an individual of due process of law or equal protection of the law by effectively prohibiting resort to test the validity or reasonableness of an order or fine. See, for example, Mercantile Trust Co. v. Texas & Pac. Ry., 51 Fed. Rep. 529 (4), 549 (14-15) (1892); Cotting v. Kansas City Stockyards Co., 183 U.S. 79-101, 22 S.Ct. 30, 46 L.Ed. 92 (1901); Ex parte Young, 209 U.S. 123, 28 S.Ct. 441, 52 L.Ed. 714 (1908); Minnesota Rate cases, 230 U.S. 352, 472, 473, 33 S.Ct. 729, 57 L.Ed. 1511 (1913); Missouri Pacific Ry. v. Nebraska, 217 U.S. 196, 207, 30 S.Ct. 461, 54 L.Ed. 727 (1910); Missouri Pacific Ry. v. Tucker, 230 U.S. 340, 349, 33 S.Ct. 961, 57 L.Ed. 1507 (1913); Bonnett v. Vallier, 136 Wis. 193 (15,16) (1908); and Coal and Coke Ry. v. Conley, 67 W.Va. 129, 132, 67 S.E. 613 (1910).

A more recent case re-stated the rule set down by Young, Wadley, Love and St. Regis line of cases. In Brown & Williamson Tobacco Corp. v. Engman, 527 F.2d 1115 (2 Cir 1975), cert. den. 426 U.S. 911 (1976), the Court stated that these cases

> "establish that one has a due process right to contest the validity of a legislative or administrative order affecting his affairs without necessarily having to face ruinous penalties if the suit is lost." 527 F.2d at 1119 (original emphasis)

It is clear that if the Department implements the system as they apparently intend, this rule will be violated. A nursing home will be faced with ruinous penalties if an appeal to contest the validity of an assessment is lost. By permitting a penalty scheme under which daily fines of up to $250 would accrue, the Department of Health is effectively depriving individuals of their right or opportunity to be heard. Cases cited above clearly show that the imposition of cumulative daily fines are of such an oppressive and burdensome nature so as to effectively preclude the opportunity of an individual to be heard.

At the hearing Mr. Breviu asked if we were seeking to have the hearing examiner declare the statute unconstitutional and we replied that we are not. Obviously a hearing examiner does not have the same authority as a court of law to do so. However, we do believe that a hearing examiner may examine and comment upon the constitutionality of a scheme as it relates to the reasonableness of a proposed rule. This is especially true where the statute does not clearly mandate the unconstitutional

scheme. Further, we believe that a rule which results in an unconstitutional system is per se unreasonable and should not be adopted.

The Department is faced with implementing a statute which is subject to at least two interpretations. As outlined earlier, we believe that it may be interpreted to avoid the daily accrual of fines while an appeal is pending, and thereby avoiding an unconstitutional scheme. Minn. Stat. §645.17 establishes certain statutory presumptions in ascertaining legislative intent. This section provides

> "In ascertaining the intention of the legislature the courts may be guided by the following presumptions:
>
> . . .
>
> (3) The legislature does not intend to violate the constitution of the United States or of this state;
>
> . . . "

Although the Department is not necessarily bound by this statutory presumption to the same extent that courts are, we believe the logic behind the presumption applies with equal force when the Department is interpreting and implementing a statute. That is, the Department should strive to avoid an unconstitutional result, if possible. We believe it is appropriate for the hearing examiner to recommend that the rule be amended to clearly state that no penalty assessment shall accrue during a good faith appeal from any assessment (see Amendment Number Nine).

Another question which we raised at the hearing deserves some additional comment. Given the current system for issuing correction orders and assessments, and given the impact of the new daily fining schedule, we asked whether the Department considered changing their procedure to allow for appeals from correction orders rather than being forced to wait for an assessment. At one time the Department did allow for appeals from correction orders. As with the question relating to daily accrual, the question of appeals from correction orders affects the reasonableness of the rules governing the amount of fines, the time period for correction, and others. Also, as with the question of daily accrual, the Department's current policy of not allowing appeals from correction orders is not mandated

by the statute. Again, this is an area where the Department could change their policy and establish a more reasonable rule. Even if the Department's apparent position that daily accrual during an appeal is mandated by law is upheld, allowing appeals from correction orders coupled with a procedure granting an extension of time for compliance when a facility files a good faith appeal might perhaps save the system from unconstitutionality.

As we stated at the hearing, we seriously question the reasonableness of any system that imposes a $50 daily penalty assessment (which amounts to $18,250 over a year's time) for the violation of a rule which the Department concedes bears "only a minimal relationship to the health, safety, treatment, comfort or well-being of a patient in a nursing home" (Statement of Need and Reasonableness, page 40). From the Department's response to questions at the hearing (T. 192-193), it is clear that the Department has not satisfied its burden of establishing facts demonstrating the reasonableness of $50/$150/$250 fine schedule. The Department admitted that they did not consider other types of fining schemes such as OSHA (T. 193). The OSHA system, for example, does not impose any fine for a de minimus violation. The Department did not give any facts that demonstrated that a 3-tier system is more reasonable than a 10-tier system, or a flexible system as was proposed in 1977. We believe that not only did the Department fail to meet its burden of showing the reasonableness of the proposed fine schedule, but that the fine schedule is patently unreasonable in light of the Department's position on the other issues we have raised.

7 MCAR §1.058 Time Periods for Correction

We would strongly suggest that the allowable time periods for correction, as stated in this rule, be minimums only. Given the extreme conplexity of the nursing home licensure rules and the variety of circumstances that may arise, it is necessary to build some flexibility into this rule. The Department's response to this suggestion at the hearing was to suggest that facilities could always resort to the procedure for requesting an extension (T.242). However, this procedure will be time-consuming and costly for both the facility and the Department and there undoubtedly will be situations where it is clear to everyone at the time of the survey that additional time will be necessary. We are recommending additional language in Amendment Number Ten to deal with this problem. Although the statute requires the Department to promulgate time periods for correction, there is nothing in the statute that prohibits the Department from including some dis-

cretion for the surveyors.

Re: §1.058.B.1. - We would suggest that the Department not insist on receiving a request for an extension prior to the expiration of the time period cited in the correction order. The inflexible enforcement of this provision might lead to facilities routinely requesting extensions, whether they are necessary or not, in order to cover themselves against some unforeseen problem that might arise on the day the period for correction expires. We are suggesting, in Amendment Number Eleven, deleting the requirement of a request prior to expiration.

Re: B.3. - Pursuant to comments we made above, we would suggest that, if the Department adopts a procedure allowing for appeals from correction orders, it might be appropriate to add another alternative to the B.3.a.2. to allow for extensions of time during a good faith appeal from a correction order.

Re: B.5. - We would suggest that the Department clarify that a facility may appeal from the denial of a request for an extension. We are proposing in Amendment Number Twelve language similar to that in waiver section. We believe that a denial would, under Chapter 15, entitle a nursing home to appeal and we think this right should be stated in the rule.

CONCLUSION

We hope that the hearing examiner and the Department will carefully consider our comments herein. Many of the problems we have indentified could be solved if the amendments we have suggested were adopted. With these few changes, the rules could help to create a fair and workable system, one that protects the interests of residents and, at the same time, recognizes the legitimate concerns of providers.

Very truly yours,

K. Craig Wildfang

K. Craig Wildfang
Staff Counsel

KCW/arr
Enclosures
cc: Commissioner George Petterson

*Amendment Number One

Proposed Amendment to 7 MCAR §1.049.C.1.

after the word "therapy" in the new language insert "or documentation by the nursing home of a good faith effort to attain complaince."

*Amendment Number Two

Proposed Amendment to 7 MCAR §1.055 U.

in the second line after "conform with" insert "one of".

*Amendment Nubmer Three

Proposed Amendment to 7 MCAR §1.044.X.1.

after the period insert a new sentence to read "The request for a waiver or variance is not an admission that the facility is in violation of the rule for which the waiver or variance is requested."

*Amendment Number Four

Proposed Amendment to 7 MCAR §1.044.X.1.

after the language suggested in Amendment Number Three insert a new sentence to read "No fine shall accrue while a request for a waiver or variance is pending."

*Amendment Number Five

Proposed Amendment to 7 MCAR §1.044 X.3.a.

delete X.3.a.(1) and renumber accordingly.

*Amendment Number Six

Proposed Amendment to 7 MCAR §1.044 X.4.

In the last sentence after the word "apply" insert "unless the alternative measures necessitate actions different in scope or nature from the actions necessary to comply with the literal requirements of the rule."

*Amendment Number Seven

Proposed Amendment to 7 MCAR §1.044.X.5.a.

In the second line, after "writing" delete "prior to its expiration date".

*Amendment Number Eight

Proposed Amendment to 7 MCAR §1.044.X.6.

Delete the entire paragraph and insert "Granting, Modified Granting, Denial and Renewal
After reviewing each waiver request received under section 2 in accordance with the criteria specified in section 3.a., the Commissioner shall make a written final decision granting, granting with modification(s), or denying such request. Such final decision shall specify the reasons upon which it is based. Such decision shall be made within 30 days after receipt of all required information."

*Amendment Number Nine

Proposed Amendment to 7 MCAR §1.057

Insert a new paragraph "D." to read:
"No penalty assessment shall accrue during a good faith appeal from any assessment."

*Amendment Number Ten

Proposed Amendment to 7 MCAR §1.058.A.

In the first sentence before the colon insert "unless the surveyor finds that there are unique circumstances which justify a longer period of time for correction."

*Amendment Number Eleven

Proposed Amendment to 7 MCAR §1.058.B.1.

delete "The request for extension of allowable period of time for correction shall be received by the Department prior to the expiration of the time period cited in the correction order. The failure to submit a request within that time period shall result in a denial of the request."

*Amendment Number Twelve

Proposed Amendment to 7 MCAR §1.058.B.

Insert a new subparagraph "6" to read:

"6. Appeal procedure. An applicant may contest the denial of a request for extension of allowable time period for correction by requesting a contested case hearing under the provisions of the Administrative Procedures Act, Minnesota Statutes, §15.0411 et. seq. The applicant shall submit, within 15 days of the receipt of the Department's decision, a written request for a hearing. The request for hearing shall set forth in detain the reasons why the applicant contends the decision of the Department should be reversed or modified. At the hearing, the applicant shall have the burden of proving that it satisfied the criteria specified in section 3. above."

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April 21, 1980

Mr. George Beck
Hearing Examiner
Office of Hearing Examiners
1745 University Avenue, Room 300
Saint Paul, Minnesota 55104

Re: In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Board and Care Homes, HLTH-80-040-GB

Dear Mr. Beck:

I.

INTRODUCTION

On behalf of this law firm, we are submitting both general and specific comments on the above-referenced proposed rules for the hearing record as a follow up to comments made at the public hearing conducted on April 1 and 2, 1980. In addition, we presented extensive testimony at the time of the public hearing and we urge you to refer to our testimony at the public hearing as well as to these comments.

The first portion of this letter will be devoted to general comments on the proposed rules as a whole. More specific comments on individual sections of the proposed rules will follow. Specific comments will be presented in the order in which the rules were considered at the public hearing.

II.

GENERAL COMMENTS

A. Statement of Need and Reasonableness.

We will make comments on the specific deficiencies in the Department's Statement of Need and Reasonableness in our comments on

the individual rules. However, a general comment which applies to the entire Statement of Need and Reasonableness is that it is replete with conclusory statements as to the need for and reasonableness of the proposed rules. It is inadequate in that it generally concludes reasonableness without looking at specific facts, alternatives, or other relevant considerations. Basically, for the most part the Statement of Need and Reasonableness is saying something is reasonable because the Department says it is reasonable. Throughout the Statement there is tremendous boot strapping without justification in fact for particular proposals.

B. Statement of Anticipated Costs and Benefits.

Minn. Stat. §144A.29, subd. 4 (1978) provides that:

> "Each rule promulgated by the commissioner of health pursuant to section 144A.01 to 144A.17 shall contain a short statement of the anticipated costs and benefits to be derived from the provisions of the rule."

The Department has apparently interpreted this section to apply only to the costs nursing homes will incur as a result of the promulgation of the rules. The language of the statute is quite clear that the Department's statement should not be so limited. Any rule relating to the operation of nursing homes and board and care homes will have a cost impact on the Department of Health itself, upon the resident and upon the Medical Assistance program. The Department has utterly failed to estimate any of those proposed costs, and the Statement of Anticipated Costs and Benefits is most deficient in that respect.

In addition, the Department has not utilized facts in its possession, or facts which could be easily acquired, to make reasonable estimates of the cost impact in various instances. Several of those instances were set forth in our testimony at the hearing. See, for example, the failure of the Department to assess the cost impact of implementing the daily tagging system when that daily tagging system necessarily requires the cost of reinspections to be paid by the nursing homes. The cost impact of the daily tagging system has not been discussed in any fashion, with the apparent assumption by the Department that because no "mandatory" requirements were being imposed by the regulation no costs would be incurred. That logic was also used in regard to other flexibilities allowed to long term care facilities or the Department in the waiver and variance area, the request for extension of time to correct, in the oxygen, dishwashing and resident fund areas. More specific discussion will be set forth in the comments on those rules, but it is clear that the Department, through its experience with predecessor systems or predecessor rules, has the ability to at least estimate a floor figure on the cost impact of the proposed flexibilities. Presumably, there is some benefit to be derived

from the provision of flexibility or from the imposition of daily fines. To be balanced against those benefits are the anticipated costs. Such was clearly the intent of the statute requiring a statement of costs and benefits to be made. The Department, by stating that it did not possess relevant facts, or that it would not estimate the potential costs for a "non-mandatory" provision, has completely ignored the directive given to it by the Legislature, and no rules can be validly promulgated until further cost and benefit estimates are made.

C. Presentation at Hearing.

The Rules of the Office of Hearing Examiners, at 9 MCAR §2.106 G., require the agency to:

> "Make its affirmative presentation of facts showing the need for and the reasonableness of the proposed rule . . .." [Emphasis supplied.]

at the hearing. The presentation by the Department witness, Mr. Tripple, merely summarized the conclusory statements made in the Statement of Need and Reasonableness. There were no facts set forth at the hearing as required by the applicable rules.

Furthermore, 9 MCAR §2.106 H. allows interested persons to address questions to the agency representatives. Such a provision was rendered meaningless by the inability of the Department witness to answer questions posed by interested persons. Those persons then had no opportunity to comment on the answers given by the Department and will not have an opportunity to do so even in written comments. In addition, when specific facts were attempted to be elicited from the Department witness, there were no facts forthcoming, clearly indicating that the Department utterly failed to make an "affirmative presentation of facts".

D. Notice of Hearing.

The Notice of Hearing, Health Exhibit No. 2, is also defective when viewed under the requirements of 9 MCAR §2.102 C. Specifically, at §2.102 C.10, there is a requirement that:

> "If required by Minn. Stat. §15.0412, subd. 7, [the Notice of Hearing must contain] a statement relating to the expenditure of public monies by local public bodies."

The Department did not file such a statement, nor did it, by its own admission at hearing after questioning, even investigate the

potential cost to local bodies of implementation of the proposed rules. Clearly the Department cannot avoid its responsibilities simply by failing to investigate the monetary impact of the proposed rules.

Minn. Stat. §15.0412, subd. 7 (1978) provides in relevant part:

> "If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, the notice of the proposed rule as required by this section shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies in the state to implement the rule for the two years immediately following adoption of the rule if the estimated total cost exceeds $100,000 in either of the two years. For purposes of this section, local public bodies shall mean officers and governing bodies of the political subdivisions of the state and other officers and bodies of less than state wide jurisdiction which have the authority to levy taxes."

The assumption of the Department seemed to be that there would be no cost to local public bodies to implement the proposed regulations. However, such is clearly not the case. Nursing homes undoubtedly will incur costs to comply with the record keeping and policy development provisions of the proposed rules. There are additional costs to nursing home residents upon admission for chest x-rays, and nursing homes are required to bear additional costs not presently borne in tuberculosis testing for employees.

Clearly the added cost to nursing homes to implement the proposed rules will be passed on to local public bodies in some respects as defined in Minn. Stat. §15.0412, subd. 7. Under Rule for Determining Welfare Per Diem Rates for Nursing Home Providers Under the Title XIX Medical Assistance Program (DPW Rule 49) those costs will be reimburseable. In fact, "the annualized cost effect of complying with federal, state, or local laws and regulations and Department of Public Welfare announced policies on care or facilities"(12 MCAR §2.049 B.1.c.(1)(c)) are reimburseable as nursing homes are permitted to project costs for complying with new state regulations as a known cost change on Rule 49 Cost Reports. Furthermore, any increased costs to medical assistance recipients will be reimbursed to the vendors of care through DPW Rule 47 (12 MCAR §2.047 Medical Assistance). Since both DPW Rule

49 and DPW Rule 47 are reimbursed through a combination of federal, state and county funds, there clearly is a cost impact on local public bodies. As an absolute minimum, the Department should be required to project the additional costs to local public bodies to determine whether or not Minn. Stat. §15.0412, subd. 7 applies. Otherwise the Department will benefit by its own wrongdoing in failing to make an adequate investigation.

E. Fiscal Notes.

Minn. Stat. §15.065 provides as follows:

> "Notwithstanding any other law to the contrary, the departments of health, public welfare, economic security, corrections and the health related boards shall not put into effect any rule, regulation, or standard, which has a fiscal impact in excess of $100,000 annually without first providing the house appropriations and the senate finance committees with fiscal notes."

While the above-quoted statute would not necessarily apply at this stage of the rule-making proceedings, it is obvious that the Department is required to put together a fiscal impact note as to the additional costs of the proposed rules. Unlike the authority discussed at Part II.C. of this letter, this section covers more than just the fiscal impact to local public bodies, making the $100,000 threshold much easier to achieve. For example, the Department itself will incur additional costs in the procedures proposed in the rules, yet it is clear that the Department has not investigated its responsibilities under this section or under Minn. Stat. §15.0412, subd. 7. Until such time as such investigation and report is made, the proposed rules cannot be validly promulgated.

F. The Rules Must Include all Matters Directly Affecting the Rights of or Procedure Available to the Rules.

On several occasions, the Department apparently took the position, both in its Statement of Need and Reasonableness and at the public hearing, that matters raised by the commentators did not need to be included in the rule being proposed or were not relevant because those matters related to internal management of the Department, to "enforcement decisions" or were matters which could have been addressed but simply were not. As will be noted more specifically with regard to certain rules, the Department has an obligation to address itself, not only in its Statement of Need and Reasonableness and presentation at the hearing but also in the text of any proposed rules as well, to matters which are necessary components of the rules

which were actually proposed by the Department.

Statutory provisions outline the Department's authority and duty when it promulgates rules. First, Minn. Stat. §15.0411, subd. 3, defines a "rule" to include:

> ". . . every agency statement of general applicability and future effect, including the amendment, suspension, or repeal thereof, made to implement or make specific the law enforced or administered by it or to govern its organization or procedure, but does not include (a) rules governing only the internal management of the agency or other agencies, and which do not directly affect the rights of or procedure available to the public; . . . ." [Emphasis supplied.]

That statement makes clear that a rule can include statements to make specific the law enforced by the agency and the procedures the agency will use to enforce or administer the law. Rules governing only the internal management need not be promulgated, but rules governing the internal management, or the enforcement policy of the Department, which do directly affect the rights of or procedures available to the public can be included in the rule.

Secondly, Minn. Stat. §15.0412, subd. 3 provides as follows:

> "Each agency shall adopt rules setting forth the nature and requirements of all formal and informal procedures related to the administration of official agency duties to the extent that those procedures directly affect the rights of or procedures available to the public." [Emphasis supplied.]

That section requires the Department to adopt rules concerning matters raised by the commentators in this proceeding, as the formal and informal procedures not addressed by the Department in the proposed rules directly affect the rights of or procedures available to the public subject to the rules.

If a proposed rule which is intended to make specific an enabling statute or to provide certain procedures does not address reasonable and likely circumstances arising under either the statute or the procedure, the rule can, and in our opinion must, address those concerns in order to be a reasonable and necessary rule. While it may be asserted that a rule as narrowly drafted is reasonable and necessary if one completely ignores the context in which the rule will be enforced, that view of the manner in which a rule must be evaluated is, in our opinion, simply absurd. Because the

Administrative Procedure Act clearly gives the Department both the authority and responsibility to enact rules on all relevant questions raised by commentators to the proposed rules here, we would urge the Hearing Examiner to critically view the proposed rules for their omission of critical matters.

G. Duty of the Hearing Examiner to Fully Assess the Extent to Which the Proposed Rules are Reasonable.

The authorities and responsibilities of a Hearing Examiner in the rule-making process are clearly spelled out in the statutes and in relevant regulations of the Office of Hearing Examiners. Minn. Stat. §15.052, subd. 3, imposes upon the Hearing Examiner the duty to:

> "(4) make a report on each proposed agency action in which the hearing examiner functioned in an official capacity, stating his findings of fact and his conclusions and recommendations, taking notice of the degree to which the agency has . . . (iii) demonstrated the need for and reasonableness of its proposed action with an affirmative presentation of facts."

That duty is a very broad one. The Office of Hearing Examiners was created as an entity wholly independent of other state offices for the very purposes of making objective and critical reviews of all proposed state agency actions. The requirement of findings, conclusions and recommendations concerning the reasonableness of proposed agency action of necessity involves a discussion of alternatives. It is impossible to conceive of concluding that one purposed action is reasonable without also discussing what actions would have been more reasonable, particularly given the amount of testimony in hearings such as this one.

The Minnesota Supreme Court case of People for Environmental Enlightenment and Responsibility (PEER), Inc. et. al. v. Minnesota Environmental Quality Council etc. and Northern States Power Co., 266 N.W.2d 858 (Minn. 1978), makes it clear that it is the duty of a Hearing Examiner to create a record upon which the agency can base its decision and upon which a court can exercise its review function. A complete record requires specific evidence and findings on all matters related to the proposed agency action. It is the duty of an administrative agency, and thus the Hearing Examiner making recommendations to an administrative agency, to consider all alternatives to its proposed actions and to make findings on why alternatives were rejected. In a contested case a Hearing Examiner noted "the Hearing Examiner must address all issues the Commissioner must

address." See the Report of the Hearing Examiner in In the Matter of the Contested Case of Northwest Health Care Center, Inc. v. Minnesota Department of Public Welfare, DPW-78-013-SM. Furthermore, as noted by a Hearing Examiner in his Report in In the Matter of the Contested Case of Willmar Nursing Home in Kindlehope v. Minnesota Department of Public Welfare, DPW-77-008-SM, April 12, 1977 ". . . it is incumbent upon the Commissioner and this Examiner to attempt to make the most appropriate or most reasonable determination, not just a reasonable determination." There is no reason or basis in law for differentiating between the responsibilities of a Hearing Examiner in a contested case and in the rule-making process.

We suggest that there are several circumstances in which the Hearing Examiner must find the proposed rule to be unnecessary or unreasonable. The first, and most obvious, is if the language of the rule itself, on its face, creates a scheme which is illegal, unworkable, or prejudically vague. A second circumstance in which the rule must be found unreasonable or unnecessary is when the facts set forth in alleged support of the proposed rule do not support the actual proposal made or do not support any rule at all. An evaluation of the rule under those circumstances must include a careful view of the supporting facts, the options available for dealing with matters raised by the facts, current procedures which address themselves to the same circumstances, and other related matters.

A third circumstance in which a rule must be found unnecessary or unreasonable is if the rule, viewed in the context in which it will operate, creates an unreasonable or unlawful scheme or procedure. There are several rules proposed by the Department in this hearing which we feel to be unreasonable in this regard. A rule implementing or creating a procedure cannot be viewed in a vacuum or assessed only on the basis of the words written within the rule itself. If the rule will conflict or overlap with other provisions, or if the rule as applied within the statutory scheme which enabled the rule in the first instance creates a result which is arbitrary, unfair, contrary to constitutional provisions, or is afflicted with some other defect, the rule must be found to be unreasonable or unnecessary. Such is especially the case if a statute is subject to two or more interpretations and a proposed rule implementing the statute chooses an unconstitutional interpretation; the proposed rule may be found unreasonable and unnecessary because it implements an illegal scheme or procedure.

A fourth circumstance in which a rule must be found unreasonable or unnecessary is when it has excluded vital matters without which the rule is confusing, misleading or otherwise incomplete. As discussed earlier in Part II.F., a rule may be found to be unreasonable if the agency ignored vital questions affecting the rights of the

public which are raised by the scheme or procedures proposed. In particular, we would draw the Hearing Examiner's attention to our more extensive comments concerning the waiver and variance, extension of time to correct, and tagging provisions of the proposed rules.

A final circumstance in which a rule must be found unreasonable is when it does not comport with the language of the enabling statute. Specifically, the enabling statute for most of the Department's proposed rules allows it only to propose minimum standards, yet many of the proposed rules are lengthy, detailed, and complex lists of procedures and policies to be followed by health care facilities. In many cases, a minimum standard would require a facility to assure health, safety, welfare, etc. of a resident in a certain area according to some basic guidelines, rather than actually requiring a detailed list of procedures to be followed.

This matter involves proposed rules, in our opinion, which are unreasonable or unnecessary, or both, for all of the above reasons. We urge the Hearing Examiner to carefully review each and every proposal made by the Department and refer to our specific comments on each rule.

III.

SPECIFIC COMMENTS

A. 7 MCAR §1.048 A.8. - Patient Funds.

1. Several commentators pointed out the need for any proposed Health Department rules to be consistent with upcoming federal regulations concerning the treatment of resident funds by long term care facilities. Both this law firm and the Minnesota Association of Health Care Facilities suggested withdrawal of this proposed rule in its entirety until the federal regulations are published. As those regulations are likely to be published by the end of April, 1980, they would be available for the Department to work with should this rule be re-proposed later in the year. There are several areas of inconsistency or overlap in the proposed federal regulations and the proposed Health Department rules, with one example being the differing requirements for placing resident funds in financial institutions.

Given the pendency of potential inconsistent federal regulations which will apply to virtually all nursing homes in Minnesota, the Department of Health has not addressed in any fashion the need for or the reasonableness of the proposed regulations which will be inconsistent, will overlap with, or will merely cause confusion when applied in conjunction with the proposed federal regulations.

We will endeavor to supply the Hearing Examiner with a copy of the new federal regulations when they are published in the Federal Register so that the Hearing Examiner can assess for himself the potential conflict or confusion caused by the two sets of regulations.

2. In its Statement of Anticipated Costs and Benefits, the Department stated that it would not estimate the cost of complying with the proposed regulation on resident funds because the provisions were "non-mandatory" to a facility. Statement of Anticipated Costs and Benefits, p. 5 . However, with the federal regulations due to be effective by the end of April, 1980, and with the uncontradicted testimony of all commentators that those regulations will require Medical Assistance participating facilities to handle resident funds, the terms of the proposed Health Department regulations will in fact be applicable to all or nearly all health care facilities in Minnesota. Thus, the Department has not fulfilled the requirement of Minn. Stat. §144A.29 by its failure to estimate the anticipated costs and benefits of the proposed resident fund rule.

Accounting for resident funds is an expensive and time consuming operation. The procedures and standards proposed by the Department will require extensive review and consultation with accountants, bookkeepers, and attorneys to appropriately implement. Considerable staff

time may be required to implement the proposed standards, if they are adopted. The Department must fulfill its statutory requirement of estimating the impact of those costs and benefits before any proposed resident fund rule can be validly promulgated. Thus, we urge the Hearing Examiner to find that the Department did not adequately support the proposed rule in its Statement of Anticipated Costs and Benefits and recommend that the rule as proposed not be adopted without further cost analysis.

3. Minn. Stat. §144A.08, subd. 1 (1978) provides the following statutory authorization to the Commissioner:

> "The commissioner of health shall establish minimum standards for the construction, maintenance, equipping and operation of nursing homes. The rules shall to the extent possible assure the health, treatment, comfort, safety and well being of nursing home residents." [Emphasis supplied].

Under that section, the Commissioner of Health through his Department has the authority only to establish minimum standards. Many of the provisions proposed here are not minimum standards, as several commentators pointed out at the hearing. See T. 62, 98. The procedure set forth is a complex procedure, with specific requirements as to location of records and contents of records. Requirements are set forth as to what sort of accounts money can be kept in and what arrangements multi-facility corporations have to make for resident funds. A minimum standard in this area would merely provide with some basic guidelines the types of safeguards to be provided to patients and residents. The Department has exceeded its statutory mandate in the manner in which this rule was drafted and must be rejected for that reason.

4. The Statement of Need and Reasonableness in support of this proposed rule is a perfect example of the general comments about the inadequacies of the Statement of Need and Reasonableness made earlier at Part II.A. This rule must be rejected as the Department's alleged support of it is woefully inadequate. A few examples:

a. At p. 27 of the Statement of Need and Reasonableness, concerning 7 MCAR §1.048 A.8.c.(1)-(3), the Department justifies the proposed provisions by stating: "These are reasonable steps for the protection of residents' funds." The Statement of Need and Reasonableness does not even attempt to point out the facts supporting the provisions or the alternatives available for the protection of residents' funds.

b. At p. 29 of the Statement of Need and Reasonableness, concerning 7 MCAR §1.048 A.8.c.(5), the Department makes no attempt to present facts indicating that any amounts of money need be deposited in financial institutions. The rule is allegedly necessary "to assure for safety of funds", yet there is no citation of any problem the Department has knowledge of which would be remedied by placing personal funds in a financial institution. Again, this is one area where the proposed federal regulation may have conflicting or overlapping provisions.

c. Again at p. 29 of the Statement of Need and Reasonableness, concerning 7 MCAR §1.048 A.8.c.(7), the Department attempts to justify the three banking day provision by merely stating that "it is reasonable to require funds from outside the facility be returned within three banking days". Again, no facts are presented as to why that time period or any other time period would be reasonable, or necessary. There were no indications that money is not being returned to the residents in a timely fashion.

d. At p. 30 of the Statement of Need and Reasonableness concerning 7 MCAR §1.048 A.8.f., the Statement of Need and Reasonableness never even asserts that there have been difficulties with resident funds on the transfer of ownership. There is no support in the Statement of Need and Reasonableness for that provision.

There are other instances in the Statement of Need and Reasonableness on this proposed rule which are deficient for the same reason. We would encourage the Hearing Examiner to make a critical view of the Statement of Need and Reasonableness and note all the instances in which conclusory statements unsupported by facts or discussions of alternatives have been made.

5. As mentioned by several commentators, the provisions of proposed rule 7 MCAR §1.048 A.8.c.(4)(c)(iii) are unreasonable and unnecessary by reason of being unenforceable. That provision requires the facility to obtain receipts for purchases made with money withdrawn by individuals other than the patient or resident. It is impossible for a facility to absolutely guarantee the presence in the records of receipts of purchases made. The purchases may be such that no receipts would be available, the persons obtaining the receipt for purchases may lose or dispose of the receipts, or the purchasers may merely be unwilling to

provide the home with such receipts. Under all those circumstances, the standard set forth is completely unworkable.

The Department has not shown in its Statement of Need and Reasonableness or in its testimony at hearing in response to questioning in this regard that the precise requirements of the rule are necessary or reasonable to serve the intended purposes of the rule. The Statement of Need and Reasonableness, at p. 27, concerning this section merely states that the rule establishes the minimum components for a record-keeping system which is necessary to assure that there be proper accounting to patients and residents. Nothing in that statement indicates that the unenforceable choice made by the Department is reasonable and necessary to serve those purposes. In fact, mention was made at hearing of an alternative procedure which would require a facility to obtain a certification by the person receiving monies from a resident's account that the money will be spent for resident purposes. That type of provision is more consistent with the ability of the facility to supervise the dispersion of resident funds. Thus, in the face of the complete lack of justification by the Department for the actual procedure chosen, the rule as drafted must be rejected as unworkable.

Such a provision is particularly unsupported when the potential enforcement possibilities provided for by rule and statute are considered. A facility may be subject to a correction order and a daily accruing assessment of $150.00 should persons not under the nursing home's control fail to provide the required receipts. See proposed 7 MCAR §1.057 C.2.1. There is nothing in the rule which speaks to the efforts made by the facility to obtain such receipts or the documentation by the facility of the reasons why such receipts are unavailable, and as drafted, a facility could be subject to a daily accruing fine due solely to the actions of persons not within its control.

6. The language of the proposed rule is not consistent in the manner in which it refers to the patient, resident, guardian, or conservator. At 7 MCAR §1.048 A.8.b.(1), the language "patient's or resident's legal guardian or conservator" is used. That language is also used in 7 MCAR §1.048 A.8.c.(4)(c)(ii), according to the Department's proposed amendment to the proposed rules. See also 7 MCAR §1.048 A.c.(7). However, at other sections, with the same apparent intent, other language is used. At 7 MCAR §1.048 A.8.c.(4)(a), the language "patient's or resident's guardian, conservator, or other person designated by the patient or resident" is used. At (b) of that same section, the language "the patient's or resident's guardian, conservator or other person designated in writing by the patient or resident" is used. At 7 MCAR §1.048 A.8.d., the language "or to an authorized individual" is utilized. It is apparent that the same concepts are involved in all cited sections, and the rule as written is not reasonable for containing such internal inconsistencies.

7. Concerning 7 MCAR §1.048 A.8.a., the title of that section is "Admission Agreement", yet the text of the regulation says nothing about an admission agreement, referring instead to admission policies. That section's title should be changed so that there is no implication that the actual admission agreement form signed by the nursing home and the resident need include any of the required provisions.

8. The problem of the incompetent resident and the resulting ambiguities about the appropriate authorization for the handling of resident funds is not dealt with in the proposed regulation. Several commentators were concerned about the impact of the proposed regulations upon a facility when it was confronted with an incompetent resident without relatives or with an emergency situation. Particularly when the facility may be liable for a daily accruing fine for lack of proper authorization, the rule is not reasonable because it fails to deal with a situation which will, without fail, occur. As presently written, if a facility accepts for safekeeping the funds of an incompetent resident without a legal guardian or conservator, that facility would be subject to a correction order and an assessment even if all safeguards for that resident's funds were followed. No regulation is reasonable when it is unnecessarily vague about the responsibilities of the facility in a situation which occurs all too frequently in long term care facilities. The rule as written must thus be rejected.

9. The provision of 7 MCAR §1.048 A.8.c.(3), prohibiting the co-mingling of patient or resident funds from one facility with another facility owned by the same person, firm, partnership, etc., is purportedly justified in the Statement of Need and Reasonableness at p. 27 only by stating that there needs to be a clear identity of funds for accounting purposes and accessibility to those funds. The Statement of Need and Reasonableness does not indicate any facts indicating that co-mingling of funds from one facility with another would in fact result in indistinct or inaccurate accounting or lack of accessibility to funds. Thus, this particular section has not been justified by the Department and has not been shown to be either necessary or reasonable.

10. The provision of 7 MCAR §1.048 A.8.c.(5), requiring all funds in excess of $100.00 to be deposited in a financial institution is not supported in the Statement of Need and Reasonableness by any presentation of facts. This provision is a major change from current provisions, and thus it is necessary for the Department to undertake more justification than it has done. See also our earlier comments concerning this section at Part III.A.1. and 4.b.

11. The provision of 7 MCAR §1.048 A.8.c.(6) is ambiguous as to the manner in which accrued interest shall be prorated. The word used by the Department in the proposed rule is "attributable"; that language in no way specifies over what period of time or on what date the attribution must be figured. If the Department is to require proration of

interest, it must specify the manner in which it will be prorated. This rule is thus unreasonable by reason of its excessive vagueness.

12. Concerning the provisions of 7 MCAR §1.048 A.8.c.(7)d., requiring funds kept outside the facility to be returned within three banking days, testimony was heard at the hearing as to the alternative of five banking days. That five banking day provision had been discussed before the Nursing Home Advisory Council, and the Department has not justified the need for the reasonableness of its more restrictive three day proposed provision.

13. As testified to at hearing, the terms of 7 MCAR §1.048 A.8.f., requiring a "written verification by a public accountant" on the change of ownership in a nursing home is not reasonable by reason of its inaccuracy and vagueness. The term public accountant apparently would be construed by certified public accountants as excluding them, but the testimony of the Department witness in response to questions indicates that certified public accountants are not intended to be excluded. More importantly, the term "written verification" has no meaning within the accounting field. See T. 102-103. Accountants certify matters; they do not verify matters, and thus the rule is vague as to the content of the required statements. Similarly, the rule is absolutely silent as to what is to be verified by the accountant upon the change of ownership. The verification could encompass the current resident ledger balance and the balance in the bank accounts, it could encompass the transactions for the past year for all residents, it could conceivably encompass a verification of all transactions the past owners have had in resident accounts, and it could be that the accountants would actually have to speak to the residents and guardians. Thus, this rule is unreasonable because of its vagueness and must be rejected on that account.

In addition, the Statement of Anticipated Costs and Benefits does not address in any fashion the anticipated cost impact of this provision. Thus, the Department has failed to support the proposed rule as required by law.

B. 7 MCAR §1.046 L. - Use of Oxygen.

1. Although reference is made in 7 MCAR §1.046 L.2.c.(4) to the provisions of §1.046 L.1.a. - d., it is not entirely clear that those provisions are applicable to non-emergency use of oxygen. As that appears to be the intent of the Department, that language ought to be clarified.

2. The rule makes a basic distinction between procedures applicable to emergency use of oxygen and those applicable to non-emergency use of oxygen. Yet, nowhere does the rule define what an emergency is or what a non-emergency use would be which would bring the more comprehensive provisions of the rule into play. The Department in response to questions indicated that a dictionary definition of the word "emergency"

was contemplated, but it is our opinion that the rule as written is unnecessarily vague and, therefore, unreasonable and unnecessary.

3. This rule is another example of the Department promulgating a complex rule under the guise of promulgating minimum standards. While we have no quarrel with basic guidelines for safety and training, other provisions dealing with purely informational matters are beyond the scope of the enabling statute.

C. 7 MCAR §1.047 A. - Tuberculosis Testing for Personnel.

1. The need for continued tuberculosis testing of potential nursing home employees has not been demonstrated by the Department in its Statement of Need and Reasonableness. At p. 17, the Statement indicates that routine screening of the general population for tuberculosis is unnecessary due to the low incidence of active cases in Minnesota. It goes on to say, however, that screening of nursing home staff is still recommended by the Minnesota Department of Health's Tuberculosis Screening Unit. The Department fails to present any facts which would support the Department's position on the need for routine screening. Merely because one unit of the Department of Health recommends screening does not mean that another unit of the Department can rely on that recommendation as authoritative in a rule-making procedure without presenting some of the underlying facts which go into that recommendation. The Hearing Examiner, the public, and the Commissioner are presented with the proposed rule which they are unable to adequately evaluate. Until the Department presents affirmative facts in support of its rule, it must not be adopted. At least one speaker, Craig Wildfang, at T. 120, indicated that the thrust of the testimony before the Legislative Commission to Review Administrative Regulations was that routine screening of nursing home staff would not be necessary.

In response to questioning, the Department had no facts indicating any concerns or difficulties in the nursing home setting with tuberculosis spread through staff persons. Of the 175 cases occuring in Minnesota in 1975, the Department had no facts concerning the incidence of those cases in the nursing home setting. Under those circumstances, the need for the proposed rule has not been justified.

2. The major change made in this proposed rule is that the nursing homes would now be required to reimburse their employees for the cost of obtaining all necessary tests to demonstrate freedom from tuberculosis. In response to questioning, Mr. Tripple merely relied on the statements in the Statement of Need and Reasonableness for support of this major policy change. T. 129. The Statement of Need and Reasonableness does not contain any facts to indicate why it is necessary or reasonable for the facility to reimburse employees for testing when the employees have been responsible for such testing in the past. No facts concerning the inability of employees to pay for testing, the unwillingness

of employees to pay for testing, or the inability of the facility to guarantee appropriate testing if the facility is not responsible for it were set forth by the Department. The Department, either through its Nursing Home Division or through its Chronic Disease Control Unit, must present affirmative facts indicating the need for a change in procedure, yet it has not done so. The Statement of Need and Reasonableness merely states, at p. 18, that the responsibility for testing is placed upon the facility because it is accountable and, because it is responsible for assuring testing, it is reasonable to require reimbursement by the facility for such testing. This proposed rule must not be promulgated given the dirth of supporting evidence and facts set forth by the Department.

D. 7 MCAR §1.049 C. - Tuberculosis Testing for Patients.

1. This proposed regulation is a major change in policy and procedure from the existing regulation, and the change has not been adequately supported by the Department in its Statement of Need and Reasonableness. The current provisions of MHD 49(c)(1) are that standard Mantoux tests, or chest x-ray under certain circumstances, must be included in the medical record on admission; the chest x-ray currently required is one which can be taken within three months prior to admission.

The proposal by the Department in this proceeding is that all nursing home residents be required to have an x-ray taken 45 days prior to admission. However, this major change in policy is apparently based on one very short statement in one of the three articles referenced in the Statement of Need and Reasonableness. We understand that the statement found at p. 3 of Exhibit D to the Statement of Need and Reasonableness, an article entitled "Screening for Pulmonary Tuberculosis in Institutions" by the American Thoracic Society is the basis of the Health Department's position. That statement notes:

> "Because there is waning of tuberculin sensitivity with advancing age, the tuberculin test is not recommended as the initial screening test for older age groups."

However, the Department has not cited any affirmative facts from the Minnesota experience which would bolster the position taken in the proposed rules. At p. 17 of the Statement of Need and Reasonableness, the Department states that Minnesota has a "very low incidence of tuberculosis". Yet the Department does not attempt to assess whether the American Thoracic Society's recommendations may not be applicable to the Minnesota situation. In addition, at p. 22 of the Statement of Need and Reasonableness, the Department states that tuberculosis is more prevalent among nursing home residents than among the general population. No facts are presented anywhere in the Statement of Need and Reasonableness to support that conclusion other than the incidence of tuberculosis in persons 65 and over constituted 42 percent of the active tuberculosis cases

in Minnesota in 1978. Nor has the Department attempted to assess any problems which have arisen in the Minnesota context from the use of the standard Mantoux tuberculin test over the years since MHD 49(c)(1) was originally promulgated. Under all those circumstances, the Department has not met its burden to show by affirmative facts and evidence that the major change in policy reflected in the proposed rule is either reasonable or necessary.

2. Furthermore, as noted at the public hearing, this proposed regulation has a potential cost impact of $400,000, yet the Department made no attempt whatsoever to assess that cost in either its Statement of Need and Reasonableness or in its Statement of Anticipated Costs and Benefits. It again used the argument that Minn. Stat. §144A.29 required it only to estimate potential nursing home costs. However, as discussed above at Part II.E., that statute is much broader than the Department has apparently concluded, and the Department has utterly failed to follow its mandate. Of the potential $400,000 cost, computed from 22,000 nursing home admissions per year at $20.00 per chest x-ray, approximately two-thirds of that cost will be attributable to Medical Assistance recipients and payable by the Medical Assistance program. However, in response to questioning, the Department admitted that it had had no input from the Department of Public Welfare on the potential cost impact of this proposed rule. Particularly when such a major change in policy is proposed and when such a major cost is easily estimated, the Department must be found to have failed to substantiate its proposal through an affirmative presentation of facts.

3. Certain provisions of this regulation, as were portions of 7 MCAR §1.048 A.8., are beyond the control of the nursing home to enforce. Therefore, as a minimum standard for the operation of a nursing home, it is per se unreasonable. It is the resident and the resident's physician who have control over the completion of a chest x-ray. If the resident or the resident's physician feel that a chest x-ray taken 45 days prior to admission is not in the best medical interest of the resident, under the terms of this regulation as written, a facility would be in violation and would be subject to a correction order and a daily accruing assessment for failure of the resident to have the chest x-ray. Because this provision does not include any indication of the avenues available to the facility should a resident or physician refuse to comply with the regulation, as a minimum standard of the operation of a nursing home it is unreasonable. This is especially true when the Department has failed to substantiate the need for the regulation in the first instance. We would encourage the Hearing Examiner to take judicial note of the growing controversy over the unnecessary use of x-rays and also take note of the responsibility of the resident and the resident's physician to determine appropriate care for the resident in assessing the unreasonableness of this regulation. As drafted, any resident who is admitted to a hospital 50 days before admission to a nursing home and who had a chest x-ray upon hospital admission, would have to have another chest x-ray

before admission to the nursing home. It is more than likely that a patient under careful observation in the hospital for an extended period of time who showed freedom from tuberculosis through a chest x-ray five days prior to the limit set forth in the regulation will not be willing to undergo yet another chest x-ray, particularly when the patient is aged. Under all these circumstances, this regulation is unreasonable.

4. The Department has not set forth any facts whatsoever to substantiate its proposed change to an x-ray in a 45-day period prior to admission from the Mantoux test or chest x-ray in a three-month period prior to admission contained in the existing regulation. For all the reasons set forth above, especially in view of the control over appropriate medical care exercised by the resident and the resident's physician, this particular provision of the rule cannot be found to have been supported by affirmative facts and evidence.

E. 7 MCAR §1.048 A.4. - Retention of Records.

No comments.

F. 7 MCAR §1.052 A.1. - Double Beds.

No comments.

G. 7 MCAR §1.053 F. - Medication Disposal.

No comments.

H. 7 MCAR §1.055 U. - Chemical Sanitizing of Dishes.

No comments.

I. 7 MCAR §1.064 A.3.f. - Locks on Doors.

No comments.

J. 7 MCAR §1.044 X.- Variance and Waivers.

1. This rule proposes completely new procedures and standards through which the Department can evaluate waiver or variance requests. Because the procedure is entirely new, there are many questions concerning its content and effect with which no one has yet had any experience. There are a number of blatant omissions in the proposed rule which, in our opinion, leaves the rule as drafted unreasonable for its failure to address obvious problems which directly affect the rights of persons utilizing the procedures, or the procedures available to them. See Part II.F. herein.

A waiver or a variance request necessarily involves facilities not in literal compliance with the terms of the rule from which a

variance or waiver is requested. As the Hearing Examiner well knows, if a facility is not in compliance with the terms of a rule, it is subject to a correction order and a penalty assessment, those penalty assessments to be daily accruing in the future. If a facility, whether or not it has been issued a correction order, makes a request to the Department to in some way vary from the literal terms of an applicable regulation or to not comply with the regulation at all, it has in effect admitted that a violation of the regulation is or was occurring. Should a facility submit a waiver or variance request which is then denied by the Department, it may well find itself subject to very careful attention by the Department. The proposed rules do not address themselves to several eventualities which will certainly arise under the provision of the rules and surrounding procedures. The risks and uncertainties which arise under the current language of the regulation are such that many facilities will choose not to utilize the procedures allowed even though the Department itself recognizes the need for the flexibilities which a waiver or a variance would bring. Thus, the rule as drafted, because it directly affects the rights of providers to utilize the provisions under appropriate circumstances, is unreasonable as written.

The first unreasonable deficiency in the proposed rule is the effect a waiver request may have against a facility in any later enforcement proceedings under the rule from which the waiver or variance is requested. As the regulation is written, the Department could very well utilize a waiver request, which necessarily admits the existence of a violation, to prove that a violation existed at certain times. We feel that a waiver or variance request is very similar to information offered in settlement negotiations or in consent agreements, under which two parties reach an accommodation satisfactory to both without either party admitting any fault or wrongdoing. This crucial deficiency in the regulation as drafted is easily made whole by the addition of language to Section X.1. similar to the following:

> "No request under this subdivision shall constitute an admission of violation of any provision of these rules for any purposes."

That proposed language would require the Department to prove the existence of regulatory violations at relevant time periods just as it is now required to prove it, that is through the observations of surveyors or the testimony of facility witnesses. It would merely maintain the current procedures and would provide a clear statement that the Department cannot rely on a waiver request to meet its burden of proof. As it emerged under questioning by Mr. Wildfang at the hearing, the Department may be able to and intends to utilize a waiver request to meet its burden of proof in an assessment hearing under the current language; and such a result is not consistent with the purposes of a waiver or variance procedure.

A second deficiency in the language as proposed is its failure to address the effect of a waiver request upon Department enforcement

procedures during the Department's consideration of the waiver or variance request. Under Minn. Stat. §144A.10, subd. 4, and under proposed 7 MCAR §1.058 A., a facility is given a certain amount of time to correct any alleged deficiencies; after the expiration of that time period, a facility is subject to reinspection by the Department and the possibility of daily accruing penalties for failure to comply with a correction order. If a facility has a waiver or variance request pending with the Department when the time period for correction runs, under the current language of the proposed regulation a penalty assessment could begin accruing even while the Department is considering a waiver or variance request. Under the principles of due process and basic fairness, such an event, in our opinion, must not occur; the proposed rule as drafted is unreasonable for not clarifying a crucial issue which will undoubtedly be raised under the proposed rule and procedure. At T. 153, Mr. Breviu noted that the Department would not state at hearing that a waiver or variance request would operate to stay the accrual of a fine, apparently even if the Department itself is delaying on its resolution of a request.

A third manner in which the proposed rule is unreasonable is that it does not provide a nursing home a time period for correction of an alleged violation following the Department's denial of the request. Conceivably, the day after the Department denies the waiver request, it could visit a facility to issue a correction order or daily accruing penalty assessment without the facility having a time to remedy any alleged violations. As denial of waiver requests are in all certainty going to occur under the procedures set forth, this deficiency makes the rule as drafted unreasonable for not including a provision for a crucial and certain event.

Both this deficiency and the previous deficiency could easily be corrected by the addition of language to subsection X.1. similar to the following:

> "The Department will not issue a correction order or penalty assessment for any alleged violation of a provision of these rules during the pendency of a request under this subdivision for a variance or waiver of that provision or during the applicable time period for correction under 7 MCAR §1.058 after denial of such a request."

2. The variance or waiver can apparently be granted for different lengths of time, yet the proposed rule does not provide any criteria to guide the request or the Department to evaluate the length of time for which a waiver or variance will be granted.

3. The criteria for evaluation, at 7 MCAR §1.044 X.3.a., requires, at (1), that the "alternative measures to be taken", be found to be "equivalent or superior to those prescribed in the rules", yet the Department's Statement of Need and Reasonableness clearly defines a

waiver as permission not to comply at all with the provisions of a rule. Examples of situations in which a waiver or variance would be appropriate yet inconsistent with the literal language of the proposed regulation are requests dealing with physical plant deficiencies such a narrow corridors, door widths, or room size. In those situations there are very few, if any, alternatives a facility has, let alone alternatives which are "equivalent or superior to those prescribed" in the rules. If permanent waivers for certain physical plant deficiencies under appropriate circumstances are to be granted, as appears to be the Department's intent, the current language does not give the Department that authority. The "alternative measures" requirement in the rule as drafted is overbroad and is contrary to the Department's own justification for the rule and thus, without amendment or complete elimination, is unreasonable.

The third criteria for evaluating a waiver or variance request, found at 7 MCAR §1.044 X.3.a.(3), requires a finding that literal application of the rule or rules would impose an undue burden. However, the Statement of Need and Reasonableness at p. 4 clearly states that a waiver or variance request would be considered in those situations in which an innovative approach to long term care is being recommended. Under the terms of the regulation as drafted, it would in all likelihood be impossible for a facility proposing a waiver or variance involving a creative approach to in fact obtain one. We urge that the three criteria for evaluation of a request as proposed do not comply with the Department's apparent intent in drafting the regulation and the rule is therefore unreasonable.

4. We concur in the testimony of Craig Wildfang at T. 157-158, in which he pointed out that the alternative measures undertaken pursuant to a variance or waiver may in fact require a longer period of time to complete than is allowed in the applicable time period for correction for the regulation waived or varied. The Department has not in any way addressed that likelihood in its Statement of Need and Reasonableness, stating only that there would be "no way to enforce the alternative measures" without the provisions quoted. There is no factual basis in the Statement of Need and Reasonableness for that provision, especially in light of the concerns raised by Mr. Wildfang.

The proposed rule also does not have any provision for a time limit on the Department in which to evaluate a waiver or variance request. This is a particularly troublesome omission when viewed alongside the failure of the rule to address in any fashion the enforcement policy of the Department during the pendency of a waiver request. Conceivably, the Department could spend weeks or months evaluating a waiver request and have its surveyors visiting the facility issuing correction orders and assessments while the request is pending. Such a lack of standards for Department action directly affects the rights of the persons affected by the provisions and thus does not comport with statutory requirements for the promulgation of rules. See Part II.F. herein.

5. While 7 MCAR §1.044 X.6. provides that a decision of the Department to deny, revoke or refuse to renew a waiver or variance request shall be in writing, it contains no requirement that the Department state the reasons for the denial. When read in conjunction with the provisions of 7 MCAR §1.044 X.7., which requires a person appealing from a denial of a request to state in detail the reasons why the decision should be reversed or modified, when an applicant is unable to determine the reasons that the Department has given for denial, it may be quite impossible for him to comply with the later sections of the proposed regulation. At hearing, the Department was unable to address in any meaningful fashion the need for the provisions as drafted, and thus the omission of such a provision is unreasonable.

6. The subtle differences between a waiver request, a variance request, or a request of an extension of the time period for correction under proposed 7 MCAR §1.058 B. may not be readily apparent, and it is likely that a facility may make a request for an extension of time which in fact is a request for a variance or a waiver; the opposite may also occur. Under the proposed regulations, as written, such a request would have to be denied by the Department for failure to meet the regulatory criteria. The rule omits a crucial procedure whereby the Department will consider a request for what it actually is, rather than denying the request entirely. When coupled with the provisions in the rule that the Department's reasons for denying a request need not be set forth, a facility may be in a position of having its request denied merely because it asked for the wrong thing. Similarly, there is no apparent provision in the rule for the Department to modify a request which is made. Under the strict language of the regulation, if the request made is for a six-month waiver or variance and the Department feels a waiver for three months is appropriate, it will have to deny that request rather than merely coming back with a modification or counterproposal.

7. There are no provisions in the proposed rule for oral or personal discussions with representatives of the Department on a waiver request. It is likely that circumstances will arise where a physical viewing of the facility or a round table discussion of the circumstances will be required, and the language of the rule as proposed could serve to give the Department an argument that no oral or personal discussion on a waiver request is allowable.

8. On a renewal request for a waiver or variance, found at 7 MCAR §1.044 X.5., the facility is required to demonstrate compliance with alternative measures or conditions imposed. The rule does not specify how that demonstration of compliance should take place, and thus is unreasonable by reason of its vagueness.

9. The Statement of Need and Reasonableness does not attempt to justify why the burden of proof on a denial of a waiver or variance request is on the facility rather than on the Department. In response

to a question on this matter, at T. 175, the Department was unable to cite any legal authority for that proposed provision, citing only the Federal Life Safety Code.

10. Here as in the case with other proposed rules, the Department has not even attempted to meet its requirements under Minn. Stat. §144A.29, subd. 4, to estimate the anticipated costs of this proposed rule. The Department could very well have estimated the staff time required for processing requests so as to be able to identify potential cost impacts to the Health Department budget the proposed rules may have. It could very well also have sought input from providers as to the costs involved in compiling requests under the provisions set forth by the rule. Even if the Department has in the past had no experience with the granting of variances and waivers under its own rules, it has nevertheless received requests and inquiries from a number of facilities for similar consideration. It has had information available to it in the form of waiver requests under federal skilled and intermediate care regulations or Federal Life Safety Code which may enable it to identify costs associated with this proposed rule. In any case, the Department has utterly failed to even try to meet the statutory requirements placed upon it and thus has been unable to justify the rule as proposed.

During questioning at the hearing on this rule, it appeared that the Department chose not to make cost estimates if it did not believe such cost estimates would have any "forecasting value". Minn. Stat. §144A.29, subd. 4, does not permit the Health Department to decide for itself whether any cost estimates have forecasting value; it merely and clearly stated that cost estimates shall be done for every proposed rule. As it stands now, the public, the Department, the Hearing Examiner and the Commissioner all have absolutely no idea of the potential cost impact of this rule. No rule may be validly promulgated when basic statutory requirements have been ignored.

K. 7 MCAR §1.057 C. - Schedule of Fines.

1. This proposed regulation implements Minn. Stat. §144A.10, subds. 6, 7 and 8 (1978). That statute, and the proposed regulation as drafted by the Department, creates a system which we believe to be devoid of the most basic constitutional due process protections before the imposition of a potentially ruinous penalty assessment. The many respects in which we believe the system to be deficient have been set forth in the Plaintiff's Post Trial Memorandum of Law in the case of Minnesota Association of Health Care Facilities, et al. v. State of Minnesota, et al., Hennepin County District Court File No. 727489, portions of which are attached and incorporated herein as Attachment A. That document speaks for itself, and matters raised therein will not be repeated at length here.

The remainder of the comments we make on this proposed rule must be read by the Hearing Examiner with a clear understanding that, in our opinion, Minn. Stat. §144A.10 and the rule as proposed by the

Department are unconstitutional both together and individually because they provide no minimum procedural safeguards for good faith challenges to the imposition of a daily accruing fine. We will make comment on some of the individual characteristics of the fine system proposed, but none of these comments, or testimony at the hearing, can be construed as expressions of any approval of the daily tagging system as the Department has chosen to implement it.

In addition to matters addressed in Attachment A, there were matters raised at hearing which indicate the lack of basic fairness and common sense in the procedures and interpretations of Minn. Stat. §144A.10 posited by the Department. The Department has apparently taken the position that Minn. Stat. §144A.10 provides no administrative opportunity for a hearing on the validity of an assessment which will stop the accrual of the assessment during a good faith challenge. Both in the 1977 litigation and at hearing the Department asserted that any basic due process protections to which nursing homes may be entitled were available in the courts rather than in the administrative hearing process. A nursing home asserting that a penalty assessment was inappropriate would have the opportunity to challenge it without the accrual of the penalty only by proceeding immediately to court after the issuance of a correction order or assessment. Yet, because Minn. Stat. §144.10, subd. 8 does provide for an administrative appeal from the issuance of a penalty assessment, the Department stated at hearing that a nursing home bringing the question of the validity of an assessment to the District Court for determination on the inappropriateness of the daily accruing fine under the circumstances may be faced with the Department's opposition to that action on the basis that the action may not be ripe, or that the nursing home may have failed to exhaust administrative remedies or did not give credence to the doctrine of primary jurisdiction. T. 216-217. The interpretation of the Department, and the apparent application of the statute and regulation the Department will make, amounts to a legal Catch-22: a facility may choose to challenge the accrual of a daily fine in an administrative process, during which the fines would accrue on a daily basis and which must be paid if the facility's good faith defense is rejected by the Commissioner or, if it chooses to go directly to court, it may be faced with an argument that a court action is not appropriate for failure to exhaust administrative remedies. Basic principles of due process and fairness forbid the imposition of this meaningless choice upon a facility which has a good faith challenge to the imposition of a penalty assessment. The natural result of the system implemented by the Department in this proposed rule is that nursing homes with good faith challenges to a penalty assessment will be deterred from having their concerns evaluated by an impartial judicial entity.

For these reasons, as more fully expanded upon at hearing and in the Post Trial Memorandum attached hereto, we feel that the procedure being proposed and implemented in 7 MCAR §1.057 C. is unconstitutional and must be rejected as unreasonable and unnecessary.

2. This proposed rule is a very simple rule on its face. It merely sets forth the fine level which will be imposed for any alleged violation of the specified regulations. However, this rule in fact does much more than its literal terms indicate. Because of the Department's failure to address in the language of the rule several eventualities which will certainly arise through the application of the rule, this rule is woefully deficient as well as unreasonable and unnecessary as written. The Department of Health itself, in the above-cited case of Minnesota Association of Health Care Facilities, et al. v. State of Minnesota, et al., stated that in 1977 Minn. Stat. §144.10 could not be adequately reviewed by the court because the entire system set forth by the statute had not yet been made clear by the Department through the rule-making procedure. Yet, three years later when the Department finally does attempt to promulgate a rule to implement the statute, the language of the rule itself includes only dollar amounts. The Department cannot have it both ways, and must not be found to be required to set forth many other considerations in this proposed rule before it can be validly promulgated.

In the Defendants' Trial Memorandum dated April 7, 1977, the then Minnesota Board of Health and Commissioner of Health made a number of statements concerning the "speculative" nature of the system to be implemented by the Department under Minn. Stat. §144.10. At pp. 3 and 4, after stating that the Board had not yet been able to bring a draft rule on a schedule of fines to hearing prior to the litigation, the Board stated:

> "Naturally, the full process by which Section 10 will be implemented by defendant Board cannot be currently ascertained except by speculation."

Later in the Memorandum, the Department stated that the statute itself did not address crucial matters without which a determination on the validity of the system was allegedly premature:

> "Further, although Section 10 calls for the imposition of a fine in accordance with a schedule of fines, it is not yet possible to determine if these fines will be automatic since no schedule of fines has yet been promulgated. It may be that the schedule of fines will permit mitigating circumstances to militate against all, or part of, an assessment." p. 19.

Nowhere in the proposed rule itself or in its Statement of Need and Reasonableness does the Department address the matters which had been alluded to by the Department in support of its argument that in 1977 the statute alone could not be reviewed.

Among the matters not addressed in this proposed rule is the

position of the Department about the availability of an administrative appeal from the issuance of a correction order so as to have the validity of that correction order determined in a situation where a daily fine will not be accruing. Minn. Stat. §144A.10 does not prohibit an administrative appeal from the correction order, and the Department's position on this question was not articulated by the Department on the ground that it was an "enforcement question". See T. 188-189.

The language as proposed also omits any reference to the procedures for assessing the cost of the re-reinspection required by Minn. Stat. §144.10, subd. 7. Similarly, the regulation does not address itself to the procedures or policies of the Department in implementing the statute which requires it to respond within a three-day time period to a notice of compliance. It also does not address what may happen to a facility which, upon that re-reinspection, is still found to be in non-compliance. A number of other omissions of similar nature were noted at T. 208-214 and will not be repeated here. Each one of those considerations are policies or procedures, enforcement positions, or internal procedures which do affect the rights of or procedures available to the public and thus must be addressed under the terms of Minn. Stat. §15.0412, subd. 3.

3. Notwithstanding our basic objections to the entire concept of the daily accruing fine system as apparently proposed by the Department under Minn. Stat. §144A.10, we also find it imperative to point out that the Department has utterly failed to justify the three tiered assessment system it proposes in this rule. We initially draw the Hearing Examiner's attention to the existing penalty rule, MHD 57, which is proposed to be amended in this hearing. In MHD 57, there are two possible single instance fines to be assessed, $50 for violation of certain regulations and $250 for violations of other regulations. In making the proposal it does in this proceeding, the Department's minimum figure for a daily accruing fine, tied to violations of regulations which would have a minimal impact on the health, welfare, etc. of residents in a nursing home, is at the same $50 figure which currently is imposed as a single instance fine for violation of similar regulations. Nowhere in the Statement of Need and Reasonableness or in response to questioning at hearing did the Department address the need for or reasonableness of keeping the minimum daily accruing fine at the same level as the minimum single instance fine was under the previous system.

In response to questioning, the Department relied on its Statement of Need and Reasonableness, stated that it had not specifically reviewed or was not prepared to comment on other penalty assessment schemes, and apparently had made no evaluation of the need for the actual scale chosen. At T. 192, the following exhange was had:

> "[Mr. Wildfang] . . . I wonder if the Department would comment on what they see as the reasonableness of a $50.00 a day fine which could conceivably accrue

to $18,000.00 a year for the violation of a rule which the Department has conceded there is only a minimal relationship to the purposes for which a nursing home exist.

MR. TRIPPLE: I don't know if there really is a response to that. The ranges were established by the Department. We felt that they were reasonable to base the severity of the fine on the type of rule that was in violation and we selected the $50.00, $150.00 and $250.00 range.

. . .

MR. WILDFANG: Did the Department consider selecting a figure lower than $50.00?

MR. TRIPPLE: I guess I cannot really respond to that right now . . .."

From that exchange we feel it can be fairly concluded that the Department did not in fact have any reasoned justification for picking the daily accruing figures that are proposed here. Similarly, in the Statement of Need and Reasonableness at pp. 39-40, the Department makes absolutely no attempt to articulate the facts allegedly supporting the figures actually picked. The only justification the Department undertakes is for its three tiered system.

The Department has had vast experience in the issuance of penalty assessments over the years. Presumably, it has evaluated the system it has been enforcing and has come to some conclusions which could be presented in support of a change in that procedure. The Department has not even attempted to do so in this proceeding. It has not stated that there has been widespread non-compliance with regulations which would be cured by the daily accruing fine set at single instance levels. It apparently just picked the three figures out of the air and concluded that those figures were reasonable, without any analysis whatsoever. The statutes and regulations governing the Department in a rule promulgation hearing do not permit a rule to be promulgated on the basis of the Department's conclusions that certain figures were reasonable, and this rule must be carefully reviewed by the Hearing Examiner.

It is no justification for the actual choices made by the Department that some rule implementing a daily fine system is mandated by the enabling statute. We agree that the statute requires a daily fine system to be implemented by the Department. However, that statute clearly gives the Department the authority to issue fines in the range of $0 to $250, and the Department has acted by failing to justify the choices actually made within that range. Thus, the need for "some" rule under the enabling statute does not justify the rule as actually proposed by the Department.

4. Again, the Department has utterly failed to undertake the analysis of anticipated costs and benefits that Minn. Stat. §144A.29, subd. 4 requires. At T. 230, the Department attorney appears to imply that, because the new enforcement scheme may be somewhat different from the current enforcement scheme, no reasonable cost estimates can be made. To the contrary, when a somewhat different enforcement scheme is going into effect, the need for cost analysis under the terms of the statute is even more crucial. Furthermore, Minn. Stat. §144A.29, subd. 4 does not say that there are circumstances in which the Department does not need to estimate costs. It simply requires it to estimate those costs, and the Department has ignored that directive.

Among the costs which ought to have been estimated is the cost of the reinspection to be imposed upon facilities under the statute which is now being implemented by the proposed rule. The Department has apparently ignored the fact that previously unimplemented portions of the statute will become effective under the terms of the proposed rule and has ignored the cost associated with that implementation.

Furthermore, the Department has failed to estimate the cost impact of the daily accruing of penalty assessments to facilities who do choose to appeal such an assessment. The Department is fully able to make some reasonable estimates of the times involved in the appeal process during which fines will continue to accrue under the Department's apparent reading of the statute. The Department has also failed to estimate its own costs in implementing this statute and has apparently not looked at the number of assessments and correction orders it has processed in the past to give it some method of estimating costs for the future.

Finally, the cost impact and potential benefit of the actual fine schedule chosen was not estimated by the Department. Presumably, although never articulated by the Department, the Department did have reasons for choosing the daily accruing fine levels that it did. The anticipated benefits of the fine schedule are required to be enumerated alongside of the anticipated costs of the system so that the Legislature's directive is followed.

Thus, this rule must be rejected for its complete failure to follow statutory requirements.

L. 7 MCAR §1.058 - Time Periods for Correction and Extension Requests.

1. Currently, when correction orders are issued to long term care facilities, those correction orders specify a time period for correction. In proposed rule 7 MCAR §1.058 A., the Department is proposing to codify time periods for correction. However, in attempting to justify the proposals actually made, the Statement of Need and Reasonableness does not include any discussion of the current time periods for correction and the experience the Department has had in utilizing those time periods

for correction. The public, the Hearing Examiner and the Commissioner are thus not provided with any facts from the Department's experience which allows them to make intelligent evaluation of the proposals the Department has made here. All the Department attempted to do in its Statement of Need and Reasonableness is make conclusions concerning reasonable lengths of time for attaining compliance with the rule, and, from reading the Department's statement, one would never know that the Department had in fact been setting times to correct alleged deficiencies for several years.

For example, a number of sections allow a fourteen-day period for correction when the Department sees correction as involving development of internal policies. However, in response to questions about the facts the Department is relying on to justify a fourteen-day period for the development of internal policies, the Department witnesses were unable to respond with any facts gained from its experience. Similarly, the Department could not testify to any facts which would support its conclusion that a sixty-day period is reasonable when a facility is required to obtain bids. See T. 263.

This rule and the alleged support given to it by the Department are prime examples of the arguments made previously in Part II.G., that an assessment of the reasonableness and necessity for actual Department proposals requires a discussion of experience, facts, alternatives and other related matters. Such has not been provided by the Department and this rule must be found to have been unsupported both as to its need and to its reasonableness.

2. This proposed rule requires that the extension request be made by the administrator of the nursing home. The variance and waiver provisions of 7 MCAR §1.044 X. do not require the request to be made by the administrator. The Department in its Statement of Need and Reasonableness has made no effort to justify why the administrator is required to make the request for an extension of the time period for correction and not the seemingly more serious request for a variance or a waiver. The rationale allegedly supporting the requirement for the administrator to make requests for extension of time to correct, if applicable at all, applies with even greater force to the waiver and variance request, and thus the absence of such a requirement under the variance and waiver indicates the lack of necessity for the requirement in this proposed rule.

Furthermore, as testified to at hearing, the requirement that only the administrator may request an extension does not comport with the Department's own statements in the Statement of Need and Reasonableness and may not comport with the authority of the controlling person or the governing body of the facility. The Statement of Need and Reasonableness at p. 69 states that the Department will accept the individual in charge in the absence of an administrator if an extension request is made. The rule itself does not provide that flexibility, and if that was the intent of the Department in writing it, that matter should be clarified.

Secondly, the controlling persons have many responsibilities to the proper operation of the facility under Minn. Stat. Chap. 144A, and those persons must be recognized in making extension requests consistent with their responsibilities to the facility.

3. This rule has a number of the same deficiencies discussed at some length in the waiver and variance provision of 7 MCAR §1.044 X., and they will only be summarily mentioned in this context. The rule is critically deficient in its failure to indicate the impact on a facility upon a denial of an extension request when the time period for correction then runs out immediately upon a denial of the extension request. Presumably, the facility would be subject to immediate enforcement through a daily accruing fine. We would propose language similar to that proposed under the waiver and variance provision, namely that there will be an insulated period following denial of a request for an extension during which the Department will not reinspect for purposes of issuing a possible penalty assessment.

There are no time limits on the Department's action on a request for an extension, and there are no guidelines as to the vulnerability of facilities to possible enforcement procedures if the Department should not render its decision before the end of the time period for correction.

According to the terms of 7 MCAR §1.058 B.1., a request for an extension will be denied if the request is not submitted within the time period for correction. That rule has not been justified in the Statement of Need and Reasonableness when there are circumstances beyond the facility's control for the failure to make a request in the appropriate time period. All other criteria for granting an extension may be met, but the Department appears bound to deny an extension request even for good cause shown. Under the circumstances, such a provision is unreasonable and has not been justified by the Department either at the hearing or through its Statement of Need and Reasonableness. All the Department stated in its Statement of Need and Reasonableness was that "there must be some mechanism to assure that facilities will not delay in making efforts to attain compliance."; the need for "some mechanism" does not justify, without more discussion of alternatives, the actual mechanism chosen.

We have previously expressed concern over the lack of standards governing the manner in which the Department will treat a request for an extension which is in fact more appropriately a waiver or variance request. We refer the Hearing Examiner to the discussion on this subject at Part III.J.6. In addition, there are no provisions here for Department modification of the extension request, similar to the lack of provision in the waiver and variance section for a modification of the waiver or variance request. See Part III.J.6.

4. At 7 MCAR §1.058 B.2.b., the proposed rule requires that an oral request for extension must be confirmed in writing within 24 hours.

Such a provision is not reasonable if an extension request is made on a Friday afternoon. The intent of the Department to obtain timely written affirmation could certainly be met more reasonably by a one working day requirement.

5. Here, as in the waiver and variance rule, there are no criteria to guide either the nursing home or the Department in determining what an appropriate length of time an extension will be requested and granted for. The rule thus leaves a crucial matter unaddressed, as the whole purpose of the rule is to obtain an extension of time to comply with a correction order.

6. Once again, the Department in this rule has not made the required cost estimates for processing extension requests within the Department or cost estimates for facilities who may develop an extension request, as required by Minn. Stat. §144A.29, subd. 4 (1978). The Department, under questioning, was unable to provide any facts about the number of extension requests the Department has received under the informal procedures currently existing to enable it to estimate the likely costs in the future. It appears that the Department has on this rule, as well as on other rules, merely ignored the statutory requirement that an attempt to estimate costs be made. The Department has relied on its rationale that no cost estimate need be made for a "non-mandatory" procedure made available to long term care facilities. The purpose of enacting this rule was to accommodate the requests for extension the Department had received in the past and would receive in the future, and the cost of the actual procedures proposed along with the flexibility it allows must be assessed as required by the legislature. Thus, this rule, as others, has not been appropriately supported by the Department.

IV.

CONCLUSION

For all the reasons discussed in the preceding commentary, we encourage the Hearing Examiner to thoughtfully examine the language of the proposed rules, the purported justification for the rules offered by the Department, the failure of the Department to follow statutory commands, and all other matters raised here and at hearing and to fully evaluate in his Report every aspect of the matters raised.

Very truly yours,

BROEKER, HARTFELDT, HEDGES & GRANT

By_____
Barbara J. Blumer

BJB:ml
Attachments
bcc: JMB/BTJ
cc: LaVonne Hagemeyer
Craig Wildfang and J. I. Green
Steve Chies

STATE OF MINNESOTA

COUNTY OF HENNEPIN

DISTRICT COURT

FOURTH JUDICIAL DISTRICT

File No. 727489

Minnesota Association of Health Care Facilities, a Minnesota non-profit corporation; Waite Park Nursing Home, Inc., a Minnesota corporation; Friendship Homes, Inc., d/b/a Friendship Manor, a Minnesota non-profit corporation; Mala Strana, Nursing Home of New Prague, a Minnesota partnership; Valley View Manor Nursing Home, City of Lamberton; Maple Manor Nursing Home of Rochester, Inc., a Minnesota corporation; Meadow Manor Nursing Home of Grand Meadow, Minnesota; Highland Chateau, Inc., a Minnesota corporation; Lake Ridge Health Care Center, Inc., a Minnesota corporation; and Southview Acres Health Care Center, Inc., a Minnesota corporation,

Plaintiffs,

vs.

State of Minnesota; Minnesota State Board of Health; Dr. Warren Lawson, Commissioner of Health; and John Doe and Richard Roe,

Defendants.

PLAINTIFFS' POST-TRIAL MEMORANDUM OF LAW

[PORTION OF MEMORANDUM OMITTED]

The following abbreviations will be used throughout this Memorandum:

	ITEM	ABBREVIATION
1.	Minnesota State Board of Health	Board
2.	Minnesota Department of Health	Department
3.	Laws of Minnesota, 1976, Chapter 173, Section 10, codified as Minn. Stat. §144A.10	Section 10
4.	Rules and Regulations of the Minnesota State Board of Health for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes	MHD Rules

EXHIBIT 3

5. Minnesota Association of Health Care Facilities — MAHCF

6. Rules of the Office of Hearing Examiners — HE Rules

[PORTION OF MEMORANDUM OMITTED]

D. "Tagging", Fining or Assessing of Nursing Homes and Boarding Care Homes.

1. Legislative History.

The 1973 Legislature of the State of Minnesota enacted Chapter 688, a portion of which was codified as Minn. Stat. §144.653. Among other things, that statute provided for assessments being issued to nursing homes and boarding care homes for violations of MHD Rules. As enacted §144.653 provided, in pertinent part, as follows:

> "Subd. 5. Correction orders. Whenever a duly authorized representative of the state board of health finds upon inspection of a facility required to be licensed under the provisions of sections 144.50 to 144.58 that the licensee of such facility is not in compliance with an applicable regulation promulgated under the administrative procedures act by the state board of health pursuant to section 144.56, a correction order shall be issued to the licensee. The correction order shall state the deficiency, cite the specific regulation violated, and specify the time allowed for correction.
>
> Subd. 6. Reinspections; fines. If upon reinspection it is found that the licensee of a facility required to be licensed under the provisions of sections 144.50 to 144.58 has not corrected the deficiency or deficiencies specified in the correction order, the licensee shall forfeit to the state within 15 days a sum of up to $250 for each such deficiency not corrected. For each subsequent reinspection, the licensee may be fined an additional amount for each deficiency which has not been corrected. All forfeitures shall be paid into the state treasury and credited to the general fund.
>
> Subd. 7. Recovery. Any unpaid forfeitures may be recovered by the attorney general.
>
> Subd. 8. Hearings. A licensee of a facility required to be licensed under the provisions of sections 144.50 to 144.58 is entitled to a hearing on any correction order issued to him, provided that he makes a written request therefor within 15 days of receipt by him of the correction order. Such request shall operate as a stay during the hearing and review process

of the payment of any forfeiture provided for in this section. Upon receipt of the request for a hearing, a hearing officer, who shall not be an employee of the state board of health shall be appointed by the state board of health, and the hearing officer shall promptly schedule a hearing on the matter, giving at least ten days notice of the date, time, and place of such hearing to the licensee. The hearing and review thereof shall be in accordance with the relevant provisions of the administrative procedures act.

Subd. 9. Nonlimiting. Nothing in this section shall be construed to limit the powers granted to the state board of health in section 144.55."

In 1975 the Legislature amended subdivisions 6 and 8 of Minn. Stat. §144.653 to the following:

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

Subd. 8. Hearings. A licensee of a facility required to be licensed under the provisions of sections 144.50 to 144.58 is entitled to a hearing on any notice of noncompliance with a correction order issued to him as a result of a reinspection, provided that he makes a written request therefor within 15 days of receipt by him of the notice of noncompliance with a correction order. Failure to request a hearing shall result in the forfeiture of a penalty as determined by the board in accordance with subdivision 6. A request for a hearing shall operate as a stay during the hearing and review process of the payment of any forfeiture provided for in this section. Upon receipt of the request for a hearing, a hearing officer, who shall not be an employee of the state board of health, shall be appointed by the state board of health, and the hearing officer shall promply schedule a hearing on the matter, giving at least ten days notice of the date, time, and place of the hearing to the licensee. Upon determining that the licensee of a facility required to be licensed under sections 144.50 to 144.58 has not corrected the deficiency specified in the correction order, the hearing officer shall impose a penalty as determined by the board in accordance with subdivision 6. The hearing and review thereof shall be in accordance with the relevant provisions of the administrative procedures act." Laws 1975, Chapter 310, Sections 7 and 37.

The penalty system found in Laws 1973, Chapter 688, as amended by Laws 1975, Chapter 310, is often referred to as the "tagging" system.

In 1976, Defendant State of Minnesota enacted a major reworking of laws pertaining to nursing homes and boarding care homes. The Legislature enacted Laws 1976, Chapter 173, pertaining generally to the licensure and regulation of nursing homes and boarding care homes in the State of Minnesota. In particular, the Board is to enforce MHD Rules under the "tagging" provisions of Section 10 as well as any other rules promulgated by the Board under Chapter 173.

Section 10, codified as Minn. Stat. §144A.10, provides:

[PORTION OF MEMORANDUM OMITTED]

> Subd. 4. Correction orders. Whenever a duly authorized representative of the board of health finds upon inspection of a nursing home, that the facility or controlling person or an employee of the facility is not in compliance with sections 144A.01 to 144A.17 or the rules promulgated thereunder, a correction order shall be issued to the facility. The correction order shall state the deficiency, cite the specific rule or statute violated, state the suggested method of correction, and specify the time allowed for correction. The board of health by rule shall establish a schedule of allowable time periods for correction of nursing home deficiencies.
>
> Subd. 5. Reinspections. A nursing home issued a correction order under this section shall be reinspected at the end of the period allowed for correction. If upon reinspection the representative of the board of health determines that the facility has not corrected a violation identified in the correction order, a notice of noncompliance with the correction order shall be mailed by certified mail to the nursing home. The notice shall specify the violations not corrected and the fines assessed in accordance with subdivision 6.
>
> Subd. 6. Fines. 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 promulgated by rule of the board of health. The fine shall be assessed for each day the facility remains in noncompliance and until a notice of correction is received by the board of health in accordance with subdivision 7. No fine for a specific violation may exceed $250 per day of noncompliance.

Subd. 7. Accumulation of fines. A nursing home shall promptly notify the board of health in writing when a violation noted in a notice of noncompliance is corrected. Upon receipt of written notification by the board of health, the daily fine assessed for the deficiency shall stop accruing. The facility shall be reinspected within three working days after receipt of the notification. If upon reinspection the representative of the board of health determines that a deficiency has not been corrected as indicated by the notification of compliance the daily fine assessment shall resume and the amount of fines which otherwise would have accrued during the period prior to resumption shall be added to the total assessment due from the nursing home. The board of health shall notify the nursing home of the resumption by certified mail. The nursing home may challenge the resumption as a contested case in accordance with the provisions of Minnesota Statutes, Chapter 15. Recovery of the resumed fine shall be stayed if a controlling person or his legal representative on behalf of the nursing home makes a written request for a hearing on the resumption within 15 days of receipt of the notice of resumption. The cost of a reinspection conducted pursuant to this subdivision shall be added to the total assessment due from the nursing home.

Subd. 8. Recovery of fines; hearing. Fines assessed under this section shall be payable 15 days after receipt of the notice of noncompliance and at 15 day intervals thereafter, as the fines accrue. Recovery of an assessed fine shall be stayed if a controlling person or his legal representative on behalf of the nursing home makes a written request for a hearing on the notice of noncompliance within 15 days after the home's receipt of the notice. A hearing under this subdivision shall be conducted as a contested case in accordance with Minnesota Statutes, Chapter 15. If a nursing home, after notice and opportunity for a hearing on the notice of noncompliance, or on the resumption of the fine, does not pay a properly assessed fine in accordance with this subdivision, the board of health shall notify the commissioner of public welfare who shall deduct the amount from reimbursement moneys due or to be due the facility under Minnesota Statutes, Chapter 256B. The board of health may consolidate the hearings provided for in subdivisions 7 and 8 of this section in cases in which a facility has requested hearings under both provisions. The hearings provided for in subdivisions 7 and 8 shall be held within 30 days after the request for the hearing. If a consolidated hearing is held, it shall be held within 30 days of the request which occured last.

[PORTION OF MEMORANDUM OMITTED]

Section 10 made certain changes in the enforcement of the tagging system which are of particular importance herein. Section 10 provides for a cumulative fine which can be assessed against a nursing home or boarding care home in the amount of up to $250 per day of noncompliance. Under prior law, a fine of $250 (Laws 1973, Chapter 688) or up to $1,000 (Laws 1975, Chapter 310) could be assessed against a facility. However, the fine was non-cumulative and only one fine would be assessed per violation regardless of the length of time between the issuance of the notice of noncompliance and the final decision through appeal procedures and/or payment of the fine. Furthermore, imposition (rather than recovery) of any fine was stayed until completion of the hearing and appeal process.

[PORTION OF MEMORANDUM OMITTED]

Paragraph 14 of Stipulation Number One lists those facilities receiving assessments after January 1, 1976 which requested a hearing and the dates on which various events occurred. On January 1, 1976, the Office of Hearing Examiners became effective pursuant to Minn. Stat. §15.052 (Laws 1975, Chapter 380). Prior to January 1, 1976, the Hearing Examiner was appointed by the Board and made the final determination. Under the hearing system effective January 1, 1976, the Hearing Examiner makes a recommendation to the Board but does not render the final decision. Under Section 10, the hearing must be held within 30 days of the facility's request for a hearing.

Paragraph 14, though, shows graphically that the 30 day requirement has little or no meaning since there is no requirement as to how long a Hearing Examiner may hold a case after hearing (to accommodate a briefing schedule for example). In the Lindberg Rest Home case, for example, involving 30 assessments, a hearing was held on July 23, 1976, and some nine months later there has still been no recommendation. Fines may be accruing at the rate of $7,500 per day or $225,000 a month during this period. Stipulation Number One at ¶19 (QQ) (pages 23-24). Even after a recommendation is made, the Board will not make any decision

until at least 43 days (10 days must elapse before a notice of filing - See Minn. Stat §15.0421) have elapsed after issuance of the recommendation. Stipulation Number One at ¶7 k. Thus, if Section 10 had applied to Lindberg, the fine could have been staggering.

[PORTION OF MEMORANDUM OMITTED]

III. LEGAL ARGUMENTS

A. Section 10 is Unconstitutional in its Denial of Due Process of Law and Effective Prohibition of the Petition for Redress of Grievances.

When Section 10 is subjected to the rigorous scrutiny of constitutional principles, it is clear that Section 10 is on its face unconsitutional. The basic principles of due process of law require that an individual be afforded the opportunity to be heard before that individual may be deprived of his property. It is clear that Plaintiffs have a property interest in their respective businesses, O'Connor v. Township of Chanhassen, 249 Minn. 205, 81 N.W.2d 789, at 797 (1957):

> "A right to conduct a business, together with the right to the goodwill thereof, is property within the due process clause of the constitution. See 12 Am. Jur., Constitutional Law, §§651, 655. . .".

The imposition of a fine or penalties such as required by Section 10 against Plaintiffs is a deprivation of Plaintiffs' property.

Further, any penalty cannot be of such a nature so as to effectively deny an individual his due process right to be heard. The general rule may be stated as follows:

> "Where penalties prescribed for a violation of a statute or of a state constitution are of so extreme a character as probably to prevent resort to the courts to test the validity of the statute or the constitution, there is a lack of due process of law; and a statute which provides such penalties for noncompliance with an administrative order or regulation must afford reasonable opportunity to test the validity of the order or regulation in the courts." 16A C.J.S. Constitutional Law, §640.

Thus, any penalty system must not only provide a mechanism for challenging the penalty, but the penalty itself cannot be of such a nature so as to prevent resort to that challenging mechanism.

Basic constitutional guarantees of due process and the right to petition for redress of grievances are found in both the United States and the Minnesota Constitutions. The Fourteenth Amendment to the United States Constitution, applicable to the state and subdivisions thereof, provides that:

> "No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the law."

Art. 1, §7 of the Minnesota Constitution (Restructured - 1974) also guarantees due process of law to the citizens of the State of Minnesota. Further, as is provided under the First Amendment to the United States Constitution, the State of Minnesota also guarantees to its citizens the right to redress of grievances as follows:

> "Every person is entitled to a certain remedy in the laws for all injuries or wrongs which he may receive to his person, property or character, and to obtain justice freely and without purchase, completely and without denial, promptly and without delay, conformable to the laws." Art. 1, §8, Minnesota Constitution (Restructured - 1974).

Section 10 is also violative of basic due process requirements by failing to provide a timely notice and opportunity to be heard as is required by basic constitutional law as well as by the imposition of a penalty system which effectively prohibits or will effectively prohibit resort to whatever challenging methods are available.

[PORTION OF MEMORANDUM OMITTED]

It is a fundamental right guaranteed by state and federal constitutions that an individual has the opportunity to be heard prior to the time that any deprivation may be imposed upon that person. Goldberg v. Kelly, 397 U.S. 254, 90 S. Ct. 1011, 25 L.Ed.2d 287 (1970). The opportunity to be heard must be meaningful and effectively afford the individual the right to challenge any such penalty or assessment that is levied against him. As can be seen from the terms of the statutes themselves relating to the pre- and post-January 1, 1977, issuance

of correction orders and notices of noncompliance, the only time at which a facility can challenge the imposition of such a fine is after the time that the fine is actually imposed on the facility. Prior to 1977, this may have been adequate under the principles stated in Goldberg v. Kelly, supra, as the facility could challenge the imposition of the fine and not run the risk of incurring a daily cumulative fine. The time and opportunity to be heard arguably provided reasonable protection for the facility. However, the procedure in effect on January 1, 1977, through Section 10, no longer provides an adequate method or procedure for the challenge of a correction order and notice of noncompliance levied against a facility.

The penalty system provided in Section 10 not only provides for inadequate post-imposition review, but also effectively denies an individual or nursing home or boarding care facility the opportunity to avail itself of the review procedure because of the prohibitive effect of the cumulative fine. As shown in Stipulation Number One, ¶¶14 and 19 through 21, which will be extensively analyzed below, a facility can reasonably expect to face a long delay between the time that an assessment is levied against the facility and the time at which a final determination is made. A single $250 fine accrued over one year, for example, would amount to more than $90,000. In most cases, a facility is issued more than one assessment, thus vastly increasing the potential penalty. Stipulation Number One, ¶¶19 through 21. Further, a delay of more than one year until final determination of the validity of the correction order and assessment is not uncommon.

[PORTION OF MEMORANDUM OMITTED]

When Section 10 is examined in light of numerous federal and state court decisions concerning similar penalty systems, there can be no question that it is unconstitutional. One of the leading cases striking down a penalty system involving daily cumulative fines is Oklahoma Operating Co. v. Love, 252 U.S. 331, 40 S. Ct. 333, 64 L.Ed. 596

(1920). Oklahoma Operating Co. involved the regulation by the Oklahoma Corporation Commission of rates charged businesses of a public nature. If it was determined by the Oklahoma Corporation Commission that a business was in the nature of a public business, the Commission would issue an order prohibiting the particular business from changing its rates without the prior approval of the Commission. The plaintiff in Oklahoma Operating Co. v. Love operated a laundry under an order of the Commission finding the laundry to be a public business for a few years. Plaintiff then raised its rates without the prior approval of the Commission. As a result of its actions, the plaintiff became subject to contempt proceedings. Furthermore, plaintiff was subject to a $500 per day fine for its failure or refusal to obey an order of the Commission.

The original order of the Commission declaring plaintiff therein a public business was made after notice of hearing, as was the order assessing the daily fine. Under Section 10, no hearing is provided prior to any decision made by Defendants. Instead, all determinations are made by the staff of Defendants without any recourse by the facility to challenge the issuance of the initial correction order or the assessment prior to the actual imposition of the fine. In the Oklahoma case, the order originally declaring plaintiff a public business could be appealed directly to the Oklahoma Supreme Court. However, the finding or order of the Commission relating to permissible rates could not be appealed directly. Instead, the rate could be contested only in conjunction with a contempt proceeding for failure to comply with the rate order. An appeal to the Oklahoma Supreme Court was conditioned upon the filing of a surety bond by the business in double the amount of the fine assessed, with the bond suspending the fine. In the instant case, the daily accrual of fines can be suspended only by correction of the deficiency noted in the notice of noncompliance. Such cannot be pointed to by Defendants as a method by which a facility is able to protect itself from the daily accrual of the fine in an appeal procedure. Correcting the deficiency to stay the imposition of a daily fine may well render the appeal proceedings moot because

the facility would have complied with the terms of the correction order and subsequent notice of noncompliance. However, even if a facility could still appeal the assessment after complying with the correction order, the facility would have complied with that which it is alleging has been improperly issued. Compliance may well involve the expenditure of large sums of money if the correction order is addressed to physical defects of a facility. A facility cannot be required under basic constitutional principles to be forced to choose between expending large sums of money for correcting a deficiency which it believes to be unjust in order to challenge the imposition of the assessment or not making the corrections prior, to running the risk of being subject to huge monetary fines and resultant loss of reimbursement should it not ultimately prevail.

Despite its provisions for hearings and appeals, the Oklahoma scheme was struck down forcefully by the United States Court as being in violation of due process of the law. The court stated that the limited method of appeal, coupled with the daily fines, effectively deprived the plaintiff therein of its right to be heard:

> "But the penalties, which may possibly be imposed, if he pursues this course without success, are such as might well deter even the boldest and most confident . . .. Obviously a judicial review beset by such deterrents does not satisfy the constitutional requirements, even if otherwise adequate, and therefore the provisions of the acts relating to the enforcement of the rates by penalties are unconstituional without regard to the question of the sufficiency of those rates." 252 U.S. at 336-337.

Such is even more determinative herein, as no procedures are available prior to the actual imposition of the fine for challenging any action taken by the Board, whereas in Oklahoma Operating Co. v. Love, the business could challenge the initial determination that it was a public business. Further, in Oklahoma Operating Co., a business could stay the imposition of a fine by filing a bond. However, even this was found by the court to be unconstitutional. If the use of a bond was found constitutionally defective in Oklahoma Operating Co. v. Love, then the staying mechanisms of Section 10 which effectively provide for no staying mechanism at all must also be found unconstitutionally

defective. A similar decision to that of Oklahoma Operating Co. v. Love on an analogous situation was made on the same day by the United States Supreme Court. See Oklahoma Gin Co. v. State of Oklahoma, 252 U.S. 339, 40 S. Ct. 341, 64 L.Ed. 600 (1920).

The basic principles of the Oklahoma rate cases are still viable today. A 1971 United States Ninth Circuit Court of Appeals decision struck down a penalty system under which fines of up to $1000 per day for violation could be assessed. In United States v. Pacific Coast European Conference, 451 F.2d 712 (9 Cir. 1971), the court had occasion to review a 1971 statute which prohibited, for the most part, a dual rate contract system used in international shipping. Defendants therein challenged the uniform contract that was required, if not in form then at least in substance, by the Federal Maritime Commission. The Commission had attempted to assess fines against defendants for periods extending from April 4, 1964 through December 31, 1966, at which time defendants came into compliance with the statute. The District Court had granted summary judgment for defendants on the issue of the penalty. Defendants had based their motions for summary relief on:

> "[T]he constitutional principle, established by a long line of Supreme Court cases, that statutory penalties cannot lawfully attach during the period of a bona fide judicial review of a legislative act, whether statute or administrative agency ruling.'" 451 F.2d at 715-16.

Although the District Court did not state that such was the basis for its decision favorable to defendants, the Appellate Court assumed that it was on the grounds urged by defendants. As in United States v. Pacific Cost European Conference, the same principle applies herein that no penalties can attach during a good faith challenge to an administrative ruling or statute. There is no doubt that Section 10 violates this long-standing constitutional principle prohibiting the imposition of penalties during such a challenge.

In its discussion of the case the 9th Circuit examined the "tolling doctrine" and its purposes. Such doctrine provides for the "tolling"

or suspension of penalties during the time period in which a good faith or bona fide appeal is taken. The 9th Circuit cited a 1915 United States Supreme Court case, Wadley and Southern Railway Company v. Georgia, 235 U.S. 651, 35 S. Ct. 214, 59 L.Ed. 405 (1915), in which a $5,000 per day statutory penalty was declared invalid. The Wadley decision clearly and forcefully outlines the dilemma facing an individual appealing a decision under a system in which daily cumulative fines may be assessed during the time period for appeal:

> "A statute therefore which imposes heavy penalties for violation of commands of an unascertained quality, is in its nature, somewhat akin to an ex post facto law since it punishes for an act done when the legality of the command has not been authoritatively determined. Liability to a penalty for violation of such orders, before their validity has been determined, would put the party affected in a position where he himself must at his own risk pass upon the question. He must either obey what may finally be held to be a void order, or disobey what may ultimately be held to be a lawful order. If a statute could constitutionally impose heavy penalties for violation of commands of such disputable and uncertain legality the result inevitably would be that the carrier would yield to void others, rather than risk the enormous cumulative or confiscatory punishment that might be imposed if they should thereafter be declared to be valid." 235 U.S. at 662-663 (emphasis supplied).

The Supreme Court was validly concerned with frivolous attacks on statutes or administrative orders in an attempt to evade the penalty. However, the 9th Circuit clearly stated that even though a statute or administrative order is upheld on review, such does not make an appeal frivolous and thus cause the re-imposition of the penalty. The good faith taking of an appeal to test the validity of a statute or administrative order is to be judged not by an after-the-fact determination "but by whether defendants mounted a substantial attack upon the validity of the statute or order." 451 F.2d at 719. In the instant case, it is clearly shown in Stipulation Number One at ¶19 that challenges to correction orders and notices of assessments are successful in many cases. Although the good faith nature of the challenge must be evaluated in every instance, the fact that a great percentage of assessments were dismissed by the courts, Hearing Examiner, the Board or agreement

indicates that challenges to correction orders are made on a good faith basis. Of the assessment orders issued by Defendants, in which a hearing was requested, listed in Stipulation Number One at ¶19, a total of 415 separate assessments are noted. The particular merits of 207 of these asessments were individually considered by the Department, a Hearing Examiner, the Board (if after January 1, 1976) or a district court. Of those 207 assessments, only 116 or slightly more than one-half (56%) were finally affirmed. This indicates that a significant proportion, or almost half, of those assessments which are contested and on which there has been a final determination, are not upheld for one reason or another.

[PORTION OF MEMORANDUM OMITTED]

B. Section 10 is an Unconstitutional Delegation of Power to the Board.

It is a basic principle of administrative and constitutional law that a legislature cannot delegate its powers to an administrative agency unless so authorized by the Constitution. 1 Am. Jur.2d, Administrative Law, §101; 16 Am. Jur.2d, Constitutional Law, §240 et seq. The prohibition against the delegation of legislative power is a guarantee that fundamental policy decisions will not be made by appointed officials but rather by a legislative body that is immediately responsible to the people. Gellhorn and Byse, Administrative Law, p. 76. Further, judicial power cannot be granted to an administrative agency. Minn. Const. Art. 3 §1, Art. 6 §1. State v. Erickson, 212 Minn. 218, 3 N.W.2d 231 (1942). The Constitution of the State of Minnesota explicitly provides in Article 3 that the powers of the respective branches of government are to be kept separate and thus cannot be delegated from one branch of government to another. In the case of Section 10, both legislative and judicial powers have been unlawfully and unconstitutionally delegated to the Board. Although in the area of administrative law the line between rule making and adjudication is often uncertain, clearly under Section 10 both

such powers were improperly delegated to the Board. First, the Board has been given the power to promulgate regulations without sufficient statutory guidelines. Second, the Board has been granted judicial powers in contravention of Article 3 of the Minnesota Constitution.

[PORTION OF MEMORANDUM OMITTED]

A regulatory scheme which contains standards for the imposition of a fine similar to that in City of Waukegan can be found under the Occupational Safety and Health Act (hereinafter "OSHA"). The OSHA statute itself establishes the schedule of fines for violation of OSHA regulations. The three legislatively-created levels of violations are:

1. Willful or repeated violations, for which a penalty of up to $10,000 may be assessed;
2. Serious violations, for which a penalty of up to $1,000 must be assessed; and
3. Non-serious violations, for which a penalty of up to $1,000 may be assessed.

See 29 U.S.C. §666, subd. (A) through (C); See also Minn. Stat. §182.666. The OSHA statute itself gives standards to the agency to guide it in its application of the law. The OSHA statute specifically states that:

> "[A] serious violation shall be deemed to exist in a place of employment if there is a substantial probability that death or serious physical harm could result from a condition which exists, or from one or more practices, means, methods, operations, or processes which have been adopted or are in use, in such place of employment unless the employer did not, and could not with the exercise of reasonable diligence, know of the presence of the violation." 29 U.S.C. §666(k); See also Minn. Stat. §182.651, subd. 12.

Once it is determined by the agency as to whether or not a violation is willful or repeated, serious or non-serious, based upon the facts of the particular situation, the agency then determines the amount of the fine consistent with the type of violation. The act itself in 29 U.S.C. §666(j) states the standards to be considered in determining the proper amount of the assessment. The agency is to give:

> ". . . due consideration to the appropriateness of the penalty with respect to the size of the business of the employer being charged, the gravity of violation, the good faith of the employer, and the history of previous violations."

Thus, the OSHA statute not only specifies three levels of fines for different types of violations, but further gives standards to the agency to be used in the determination of the fine once the type of violation has been determined by the agency. Under Section 10, the Board of Health is given the authority to enact regulations providing for fines of "up to $250". No guidance is given to the Board in its determination of which violations should be categorized in the various levels of fines. Further, once the system of fines has been enacted, and it must be noted that under OSHA the levels of fines were established by statute rather than by the agency, the Board is given no standards to guide it in determining the circumstances under which a fine is to be levied and the appropriateness of each such fine. The OSHA statute, like the Pollution Control Act of Illinois, contains explicit guidelines to aid the agency in its quasi-judicial function as well as to facilitate judicial review. When Section 10 is compared to OSHA and the Illinois Pollution Control Act, it is apparent that it is an unconstitutional delegation to the state agency.

[PORTION OF MEMORANDUM OMITTED]

C. Section 10 is an Impermissible Discrimination Against Health Care Facilities Governed by It.

Under Minn. Stat. §144.50 et seq., the Board is given the authority to license and regulate hospitals, sanatoriums, and other institutions "for the hospitalization or care of human beings, . . ." Minn. Stat. §144.50. Such institutions are also subject to assessments under Minn. Stat. §144.653. As stated in ¶¶8 and 10 of Stipulation Number One, the Board is given the authority to inspect, regulate, and assess, and is responsible for a number of health care facilities, including

general hospitals, convalescent and nursing care units of hospitals, nursing homes, boarding care homes, supervised living facilities, and up until January 1, 1977, free-standing out-patient surgical centers. In reviewing Section 10 in conjunction with the facts contained in ¶10 of Stipulation Number One and the entire statutory and regulatory scheme governing health care providers, it is clear that nursing homes and boarding care homes are discriminated against by the terms of Section 10 as well as by the enforcement of said statute and the regulations promulgated thereunder by the Board and Department over the years.

[PORTION OF MEMORANDUM OMITTED]

D. Section 10 is Unconstitutional by Its Imposition of a Criminal Penalty.

Section 10 imposes a system of fines for violations of various statutes as well as for violations of MHD Rules. The language of Section 10 states that the nursing home is to be assessed a "civil fine" according to the schedule of fines promulgated by the Board for each day that the nursing home is not in compliance with applicable law. Section 10, subd. 6. However, when one reviews Chapter 173 as a whole, it becomes apparent that the fine imposed by Section 10 is not a civil fine but rather, a criminal fine, thus requiring that all rights and protections incumbent in a criminal proceeding be accorded to the nursing home in question. Failure to provide such protections makes Section 10 constitutionally defective.

The language of the statute in question must be construed as a whole Governmental Research Bureau v. St. Louis County, 258 Minn. 350, 104 N.W.2d 411 (1960). The general purpose and intent of the statute must prevail over those portions thereof which are inconsistent with the general statutory purpose. Sandy v. Walter Butler Shipbuilders, 221 Minn. 213, 21 N.W.2d 612 (1946). That which is clearly inconsis-

tent with the purposes of the statute must be stricken by the Court and the Court must require that the statute be enforced in accordance with its general purposes and attendant constitutional protections and guarantees.

Prior to the enactment of Section 10, at least one Minnesota court recognized the criminal aspects of the tagging system. In Riverview Nursing Home v. Minnesota State Board of Health, Hennepin County District Court File No. 711145 (January 23, 1976), the court therein recognized that the tagging system was "quasi-criminal" in nature. With the changes brought about by Section 10 in the tagging system, it is now clear that the tagging system is, in fact, criminal.

Section 10 and other portions of Chapter 173 establish an elaborate system for enforcing applicable regulations and statutes. The Board is given the authority to issue correction orders and assessments to nursing homes for noncompliance with sections 1 through 17 of Chapter 173 as well as for violations of MHD Rules. Section 10, subd. 4 through subd. 6. Correction orders may be issued for violations by the facility itself, a controlling person, or an employee of the facility. The fine for an uncorrected violation is established by subd. 6 of Section 10 as a "civil fine". However, when Section 10 is read in conjunction with Section 8, subd. 3, that "civil" fine may, in fact, be converted into a criminal offense without any further action on the part of the Board or the facility or its controlling persons:

> "Subd. 3. Penalty. Any controlling person who establishes, conducts, manages, or operates a nursing home which incurs the following number of uncorrected violations, in any two year period, for which violations a fine was assessed and allowed to be recovered:
>
> (a) Two or more uncorrected violations which created an imminent risk of harm to a nursing home resident; or
>
> (b) Ten or more uncorrected violations of any nature, is guilty of a misdemeanor.
>
> The provisions of this subdivision shall not apply to any controlling person who had no legal authority to affect or change decisions as to the operation of the nursing home which incurred the uncorrected violations." (emphasis supplied).

Thus, if a facility incurs two or more serious violations or ten or more violations of any nature within a two year period for which a fine was assessed and then paid by the facility, the controlling person(s) will be guilty of a misdemeanor.

The criminal offense is imposed as a result of the civil fine rather than as a separate penalty system under the same statute. Instead of providing for both civil and criminal penalties, Chapter 173 institutes a "civil" penalty which, with the passage of time, may become criminal. Therefore, the initial imposition of the assessment is itself the imposition of a criminal charge, and the facility must be afforded the right to be heard. Art. 1, §6 of the Minnesota Constitution.

The fact that the facility could have requested a hearing at the time of the imposition of the assessment does not remedy the situation. The hearing afforded under Section 10 is a civil hearing subject to the provisions of Chapter 15 of the Minnesota Statutes as well as the provisions of the HE Rules. Under the hearing provisions of Section 10, the Board need only prove the alleged violation "by a preponderance of the evidence", HE Rule 217(a)(5), whereas, in a criminal proceeding, the State must prove every element of a criminal offense "beyond a reasonable doubt". Minn. Rules of Criminal Procedure 26.03, subd. 4; Re Winship, 397 U.S. 358, 364, 90 S. Ct. 1068, 1073, 25 L.Ed. 2d 368, 375 (1970). The standards for appellate review of criminal and civil hearings also differ. All appeals from agency decisions are on the record, Minn. Stat. §15.0424, subd. 6, whereas the possibility exists in a criminal proceeding for a trial de novo under certain circumstances (Minn. Rules of Criminal Procedure 28), as well as for appellate review. Minn. Rules of Criminal Procedure 29. Other rights guaranteed to criminal defendants by the Minnesota and United States Constitutions are inapplicable in administrative hearings, such as the privilege against self incrimination. U.S. Const., 5th Amend., Minn. Const. Art. 1, §7. Therefore, it is apparent that the hearing

afforded by Section 10 is violative of all guarantees of due process afforded to an individual charged with a criminal offense.

By proceeding through a hearing in which a civil burden of proof is used, a facility may be found to have violated applicable law. As a result, it will incur and be required to pay the assessment. However, that determination in a civil hearing and resultant payment of a fine can then be used by the State to charge the facility with a criminal offense.

Of equal importance is the fact that the facility may not challenge the assessment initially due to the risk of incurring a substantial fine should it not prevail. A facility may elect to pay the assessment, which may have been improperly issued, rather than risk the imposition of the cumulative fine. By doing so, however, the facility subjects itself to the provisions of Section 8 and its criminal penalties. The entire penalty system as found in Section 10 serves to deny Plaintiffs their due process rights.

The fact that an assessment can ripen into a criminal offense, and thus is itself a crime, may well preclude the Board's exercise of jurisdiction over the assessment process entirely. Art. 6, §3 of the Minnesota Constitution provides that the District Court shall have original jurisdiction in all criminal cases. This is reinforced by the provisions of Rule 26.01 of the Minn. Rules of Criminal Procedure which provides for trial by jury for felonies and gross misdemeanors in the district court and for trial by the court in cases involving misdemeanors not punishable by incarceration. It is also a generally accepted rule of administrative law that an administrative agency does not have jurisdiction over the imposition of a criminal penalty. 1 Am. Jur.2d, Administrative Law §127.

Other administrative penalty systems have been challenged in the courts as violative of constitutional rights afforded to criminal defendants or as imposing criminal penalties not within the jurisdiction of the administrative agency. For the most, these challenges

have failed either because the statute was found to be remedial in nature or provided for both civil and criminal penalties. See, for example, One Lot Stones v. U.S., 409 U.S. 232, 93 S. Ct. 489, 34 L.Ed.2d 438 (1972); Atlas Roofing Co., Inc. v. OSHRC, 518 F.2d 990 (5 Cir 1975), U. S. Appeal Pending, 96 S. Ct. 1458; 47 L.Ed.2d 731; and Frank Irey, Jr., Inc. v. OSHRC, 519 F.2d 1200 (3 Cir. 1975), U.S. Appeal Pending, 96 S. Ct. 1458, 47 L.Ed.2d 731. These cases are all readily distinguishable in that none of the statutes in question automatically transformed a "civil" penalty into a criminal offense. Chapter 173 clearly does so and Section 10 is unconstitutional for this reason.

Section 10 is violative of basic constitutional protections. It unconstitutionally delegates authority over a criminal penalty system to an administrative agency. Even if the Board could retain jurisdiction over the tagging hearing, which does not seem likely, the hearing does not afford basic due process rights guaranteed in a criminal proceeding. Further, as discussed in Section III. A. supra, the daily cumulative fines effectively prevent resort to the hearing that is available. Therefore, Section 10 must be declared unconstitutional by the Court.

IV. CONCLUSION

For reasons set out herein, Section 10 must be declared unconstitutional and the Board, Department and other Defendants enjoined from enforcing said Section 10. Finding for Plaintiffs on any of the theories raised herein justifies the granting of the relief sought. Plaintiffs respectfully request the Court to find for Plaintiffs and grant the appropriate relief.

DATED this 22nd day of March, 1977.

Respectfully submitted,

BROEKER, HEDGES & GRANT

By _____
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And _____
Kathryn E. Baerwald

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ALLENE D. EVANS
BECKY A. COMSTOCK

May 29, 1980

Dr. George R. Petterson
Commissioner of Health
Minnesota Department of
Health Building
717 Delaware Street S.E.
Minneapolis, Minnesota 55440

Re: In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Board and Care Homes, HLTH-80-040-GB

Dear Dr. Petterson:

This letter will constitute this law firm's comments under Minnesota Statutes §15.0412, subd. 4 (1978) on the Report of the Hearing Examiner in the above-entitled matter. This law firm gave extensive testimony at the hearing in the above-entitled matter and also submitted extensive written comment for inclusion in the hearing record. We will not repeat the arguments and comments contained in the transcript or which are otherwise in the record, but we encourage you to thoroughly review all input. We are of the opinion that the record makes clear that the Department has in several respects failed to demonstrate the need for and reasonableness of a portion of the proposed amendments. In making our initial comments and in writing this letter, we are not representing any individual nursing home or association of nursing homes, but our comments are made out of the considerable experience we have had in the area.

1) The Report of the Hearing Examiner noted in several respects that, while the Hearing Examiner did not find that the Department had failed to adequately demonstrate the need for and reasonableness of the proposed provisions, the Department ought nevertheless to seriously consider in its Order revision of the proposed language. We would encourage you in your review of the proposed rules to take those recommendations into consideration. Several of the Hearing Examiner's recommendations would eliminate unnecessary ambiguity, would limit unnecessary departmental discretion, and would otherwise improve functioning under the proposed

rules. We refer you specifically to Findings of Fact Nos. 21, 22, 27, 29, 49, 50, 52, 54, 57, 58, 66, 67 and 68.

2) A large portion of our oral and written comments concerned the Department's failure to estimate anticipated costs and benefits of the proposed rules. Minnesota Statutes §144A.29, subd. 4 (1978) requires a statement of the anticipated costs and benefits. On many occasions, the Department failed to estimate any costs or benefits, using the argument that the proposed rules were not "mandatory" to nursing homes in the state. At Finding of Fact No. 13, while finding the Department to have met the "minimum requirements" of the provision, the Hearing Examiner did find that the Department's methodology frustrated the legislative goals of weighing costs against benefits in the process of rule promulgation. The Hearing Examiner went on to suggest various considerations the Department could have made. We would encourage you, in reviewing the proposed rules, to take note of the respects in which the Department has failed to follow the spirit of the statute and to take appropriate action, remanding the proposed rules for a new hearing if appropriate.

3) A number of commentators noted with respect to the proposed rule on the handling of patient funds, 7 MCAR §1.048 A.8., that the rule was seriously deficient in its silence on the question of how an incompetent nursing home resident without a legal representative is to be treated under the language of the proposed rule. See Findings of Fact Nos. 17 and 22. The Department did not deal at all in the proposed rule with this difficult and serious problem, and we encourage the Commissioner to find that the rule, as presently drafted, must not be promulgated with that critical deficiency. If the proposed rule is promulgated without revision, nursing homes struggling to deal with incompetent patients without legal representatives will be in serious jeopardy of crippling fines in this ambiguous area.

In Finding of Fact No. 26, the Hearing Examiner found the Department's presentation "minimal" in support of the proposal that patient funds in excess of $100 must be deposited in a bank account. 7 MCAR §1.048 A.8.c.(5). The Department merely stated that the rule was necessary to assure the safety of patient funds without any testimony whatsoever about actual experiences when patient funds are not kept in a bank account. The Hearing Examiner also went on to conclude that the advantage of keeping funds in the bank account was "apparent". Such advantage is not in the least bit apparent unless there has been some difficulty in loss of patient funds kept in the facility. If funds are not kept in an interest-bearing account, there is no financial advantage to the patient and there may be greater difficulties in access to funds if the funds are kept outside the institution. In any case,

we urge you to conclude the obvious fact that the Department failed to present any facts supporting this proposed rule.

Concerning 7 MCAR §1.048 A.8.c.(5), neither the Hearing Examiner nor the Department replied to our comments that the proposed language is unworkably vague on the question of attribution of interest when patient funds are kept in interest-bearing accounts. The proposed rule states only that interest be pro-rated "in accordance with the amounts attributable to each patient or resident", and does not specify in what manner the attribution should be made. Therefore, it is necessary that this portion of the rule be withdrawn for vagueness as the Department withdrew Section 1.048 A.8.f. for vagueness. See Finding of Fact No. 31.

4) At Findings of Fact Nos. 34 and 38, the Hearing Examiner found that the Department had failed to make an affirmative presentation of facts showing the need for and reasonableness of two separate provisions, 7 MCAR §1.047 A. and 7 MCAR §1.049 C.1. We are in complete agreement with the Hearing Examiner on the conclusions he made and urge you to follow the Hearing Examiner's recommendation.

5) As we elaborated on in both oral testimony and written comment, we feel that the Department did not justify the level of fines chosen under the statute allowing it to impose fines of up to $250 per day. Without belaboring the point, we urge you to take a critical look at the actual proposals made by the Department, for they are not supported by any testimony concerning the need for or reasonableness of the proposals made. There was no attempt to tie the amount of the fine with the deterrent effect of a fine in various circumstances, particularly under a daily accruing system. The minimum level of fine in the daily accruing system was set at exactly the same level as a single instance fine has been set in the past, with absolutely no indication of why the much higher figure is either necessary or reasonable. The Hearing Examiner, in Finding of Fact No. 59, does not take cognizance of this gross deficiency in the Department's presentation. We urge the Commissioner to critically review the provision with an eye toward substantial revision of this rule.

6) In Finding of Fact No. 63, dealing with allowable time periods for correction, 7 MCAR §1.058, the Hearing Examiner tacitly admitted that the Department had failed to support the proposed rule with a statement of facts. The Hearing Examiner stated that "it would appear that the reasoning and conclusions contained in the Statement of Need are necessarily based upon that [the Department's] experience." (Emphasis supplied.) Without a statement by the Department of the experiences upon which it was basing the proposed rule, no reasonable person can

say that the Department met its burden to affirmatively present facts in support of its regulation. The Administrative Procedures Act requires presentation of facts precisely because one cannot conclude that all proposals by agencies are based upon or supported by its experience.

7) Finally, at Finding of Fact No. 67, the Hearing Examiner concluded that the requirement that written confirmation of a request for an extension be placed in the mail within 24 hours of an oral request was reasonable even if a weekend was involved. The Hearing Examiner, and the Department in failing to respond to our comments on this point, did not take adequate notice of the fact that the written request is not a simple matter to prepare, but must include detailed information set forth in 7 MCAR §1.058 B.2.a. The failure of the nursing home to place a written detailed request in the mail 24 hours after an oral request can result in the denial of an otherwise appropriate extension, and no one has stated why a one working day request would not be workable. We encourage you to make the requested change in this proposed rule.

As noted above, we continue to have serious objection to the entire daily fine system apparently being proposed by the Department as well as other portions of the proposals, but we will not deal with any of those arguments or concerns here; we rely in these areas on our comments already part of the record herein. We strongly urge you to carefully consider the many comments made in the course of the hearing and to either modify the proposed rules, or withdraw certain provisions of them, so as to address serious and legitimate concerns. We will be happy to discuss our comments if you so desire.

Very truly yours,

BROEKER, HARTFELDT, HEDGES & GRANT

By_____
Barbara J. Blumer

BJB:jlh

cc: Mike Tripple
John Breviu
George Beck

bcc: LaVonne Hagemeyer
Steve Chies
JMB
SMM

ECONOMICS LABORATORY, INC.
OSBORN BUILDING, ST. PAUL, MINNESOTA 55102

RESEARCH AND DEVELOPMENT DEPARTMENT TELEPHONE: (612) 451-5600

RECEIVED
Certified Mail
MAR 28 1979
457257
Executive Officer
Minn. Dept. of Health

March 26, 1979

Dr. George Pettersen
Commissioner
Minnesota Department of Health
717 Delaware Street, S. E.
Minneapolis, Minnesota 55440

Dear Dr. Pettersen:

Economics Laboratory, Inc. is a manufacturer of environmental sanitation products for the health care industries. We have long been a leader in the marketing of products for all types of warewashing systems. Having a major interest in this area, we have conducted extensive studies to evaluate low temperature - chemical sanitizing warewashing systems from the standpoint of energy conservation, cost effectiveness, cleaning efficiency and especially sanitizing efficacy.

Our microbiological data show, without a doubt, that these systems yield dishware that meets the public health requirements for a clean and sanitary end product. Supported with automated dispensers and empty drum warning signals for the sanitizer, they diminish the incidents of human failure insuring proper product and sanitizer use. These systems in no way compromise any standards or requirements for clean, sanitary dishware and utensils.

Economics Laboratory, Inc. thereby request that the Minnesota Department of Health revise the regulations for operating and licensing hospitals, nursing homes and boarding care homes to allow as an additional option, the use of low temperature - chemical sanitizing warewashing systems.

Attached you will find:

1. Exhibit J - (Petition for Adoption) Nursing and Boarding Care Homes.
2. Attachment I(n) - Deletion, changes and proposed wording for the new rule.
3. Attachment II(n) - Formal statement and justification.

4. Exhibit J - (Petition for Adoption) Hospitals.
5. Attachment I(h) - Proposed wording to be added to MHD 82(7)(bb)
6. Attachment II(h) - Formal statement and justification.
7. Exhibits: Test reports and data (confidential)
   A. File 1821
   B. File 1746
   C. File 1810
   D. Summary Report (1977-1978)

The above listed files are confidential, sensitive information submitted strictly for the purpose of this rulemaking and not to be made available for other purposes.

We appreciate your consideration of this petition.

If we can be of further service or if you have any questions, do not hesitate to contact me.

Very truly yours,

ECONOMICS LABORATORY, INC.

Charles R. McDuff

Charles R. McDuff
Director, Government Technical Affairs
Research & Development Dept.
612/451-5713

CRM/jc

Attachment

Attachments

Exhibit A — Warewashing Cost Comparison
Conventional vs Low Temperature,
R. D. LaRock, 11/1/78 (F 1821, 6C, 161)

Exhibit B — Sanitizing Efficency Of Low Temperature
Warewashing Systems, L. G. Crowell, 8/17/77
(F 1746, 6C, 154)

Exhibit C — Sanitizing Efficency Of Low Temperature
Warewashing Systems - Continuation #1746
L. G. Crowell, 9/14/78 (1810, 6C, 160)

Exhibit D — Sanitizing Efficency of Low Temperature
Warewashing Systems - Summary of the Laboratory
and Field Evaluations (1977-1978), L. G. Crowell

RECEIVED

MAR 2 8 1979

Executive Officer
Minn. Dept. of Health

Forms To Accompany Attorney General's Rules For Rulemaking

EXHIBIT J

Exhibit J: Petition for Adoption.
Suspension or Repeal of Rule

(OFFICIAL USE ONLY)

PROPOSED RULE AMENDMENT

MINNESOTA DEPARTMENT OF Health

DATE RECEIVED
DATE RESPONDED TO
ACTION TAKEN
DATE

NAME C. R. McDuff, Director, Government Technical Affairs

GROUP REPRESENTED OR TITLE Economics Laboratory, Inc.

ADDRESS Osborn Building, St. Paul, MN 55102

I hereby request that the Department named above:

(Check one)

X Adopt a new rule governing MHD-55 (u) Dishwashing (Nursing & Boarding Care Homes)

___ Suspend Rule

___ Repeal Rule

Insert here the new rule or rule change, with the exact wording proposed. Present wording of the rule is to be shown, with all wording that is to be deleted to be shown with a line drawn through the words. All proposed new wording is to be underscored.

See attachment I (n) To add (2) - Machine washing of Dishes & Utensils - Chemical Sanitizing.

(Use additional pages if necessary)

State here in as much detail and as completely as possible the reasons for your request, as the department will use as part of the basis for its decision the explanation or reasons given for your request.

1. Reduced energy consumption
2. Cost savings
3. Microbial efficacy - Clean & Sanitary Dishes
4. Compliance with standards

(additional space if necessary) See attachment II (n)

Nursing & Boarding Care Home Regulations

Economics Laboratory, Inc. requests a change in part MHD 55 "Dietary Service and Sanitation" of the Minnesota Rules and Regulations for Nursing and Boarding Care Homes as follows:

(u) Dishwashing. The dishwashing operation shall provide proper separation in the handling of soiled and clean dishes and utensils, and shall conform with the following procedures for washing, rinsing, sanitizing and drying. ~~Chemical disinfection is not acceptable~~.

(1) Machine Washing of Dishes and Utensils. Hot Water Sanitizing. The dishwashing machines shall be operated in accordance with the manufacturer's instructions which shall be posted nearby; see MHD 67(cliii). The flow pressure shall be maintained between 15 and 25 pounds per square inch (psi) at the dishwasher. The temperatures of the water shall be maintained at 140°-160°F. for the washing cycle, and at 170°F. for the rinsing and sanitizing cycle, both temperatures measured at tray level. If the same person handles both soiled and clean dishes, he shall wash his hands between operations. Dishes and utensils shall be air dried.

(2) Machine Washing of Dishes & Utensils - Chemical Sanitizing. Machines (single-tank, stationary-1 & 2 rack, door-type machines) using chemicals for sanitization may be used: Provided that:

(A) The temperature of the wash water shall not be less than 140°F. measured at the fill line.

(B) The Wash water shall be kept clean.

(C) Chemicals added for sanitization purposes shall be automatically dispensed.

(D) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(E) The chemical sanitizing rinse water temperature shall not be less than 140°F. measured at the fill line.

(F) Chemical sanitizers used shall be aqueous solutions which will provide not less than 50 ppm nor more than 200 ppm available chlorine (21 CFR 178.1010) and be EPA registered for this use.

(G) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Each machine shall be equipped with an empty drum warning signal for the sanitizer.

If the same person handles both soiled and clean dishes, he shall wash his hands between operations. Dishes and utensils shall be air dried.

~~(2)~~ (3) Hand Washing of Pots & Pans...

Attachment II(n)

ECONOMICS LABORATORY, INC.
OSBORN BUILDING, ST. PAUL, MINNESOTA 55102

RESEARCH AND DEVELOPMENT DEPARTMENT TELEPHONE: (612) 451-5600

RECEIVED
MAR 28 1979
Executive Officer
Minn. Dept. of Health

March 26, 1979

Dr. George Pettersen
Commissioner
Minnesota Dept. of Health
717 Delaware Street S. E.
Minneapolis, Minnesota 55440

Dear Dr. Pettersen:

We earnestly request that the Minnesota State Board of Health change the Minnesota Statues and Regulations for the Construction Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes to permit the use of the Low Temperature - Chemical Sanitizing Warewashing Systems in these institutions.

Our request is based on scientific studies which produced data to support the position that Low Temperature-Chemical SAnitizing Warewashing is microbiologically efficacious, energy conserving and cost effective.

Historical

The concept of low temperature warewashing in institutional and commercial establishments is by no means a recent development. For some applications such systems have been in use for 20-25 years. Chemical sanitizing has been provided for in regulations and standards at least as far back as 1962 (FDA Food Service Manual of 1962 and NSF Standards of 1965).

With mounting pressures for energy conservation and the rising costs of energy two major dishmachine manufacturers introduced, in 1975, their low temperature models. The systems were tested and documented to achieve standard, established NSF cleaning and sanitizing performance requirements.

The 1976 revised Food Service Manual published by FDA (78-2081) now specifically provides for the use of machines using wash water of not less than 120°F and a chemical sanitizing rinse of not less than 75°F. Correspondingly, we note that Minnesota does allow for these systems to be used in the hospitality industries and that such provisions are written into a recent draft revision of the rules for these industries.

A best determination from a survey we conducted was that currently only one state other than Minnesota does not fully accept the concept of low temperature - chemical sanitizing warewashing without limitations in health care facilities. However the state in question is presently revising its regulations and has under review a support document for the low temperature position.

Energy Conservation and Cost Savings

Based on comparison with conventional door type operations, both energy consumption and costs will be reduced by the adoption of a low temperature warewashing system. Cost studies indicate a net savings yield of nearly 60% of total energy used in a warewashing operation. Energy cost reductions are more than sufficient to offset the cost of the additional chemical sanitizing product. With energy costs rising at a continuing rapid rate, it is anticipated that net saving yields will increase dramatically in future years (Exhibit A).

Regulatory Compliance

Low Temperature warewashing systems comply with the regulatory programs impacting the operation.

1. FDA - sanitizing chemicals utilized by the system comply with 21 CFR 178.1010 which addresses indirect food additives utilized to control the growth of microorganisms.

2. EPA - Chemical sanitizers are classified as pesticides and must be registered for the intended use with the U. S. Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act as amended.

3. JCAH - Joint Commission on Accreditation of Hospitals Standard IV for Dietetic Services states that "the dietetic department/service shall be designed and equipped to facilitate safe, sanitary and timely provisions of food service to meet the nutritional needs of patients... Dishwashing and utensil washing equipment and techniques that assure sanitized service-ware and prevent recontamination, including monitoring of proper temperature maintenance during cleaning cycles are used." The low temperature systems do provide sanitization results at least equal to the conventional warewashing systems.

Systems Performance

Cleaning

Economics Laboratory, Inc. has conducted extensive cleaning

efficiency studies on the low temperature warewashing operations in the laboratory and in the field. These systems in no way compromise a sanitary end result. The machine itself rigidly controls the dispensing, the sequence, the timing and the actual function of the entire washing/sanitizing operation eliminating many of the instances of human error.

However, the very best system, whether low-temperature or conventional will provide a result of acceptable aesthetic and sanitary quality only if the persons directly involved in the operation are fully aware of the necessary practices and procedures required to insure that result. Employee training is the key and cannot be overemphasized. Maintaining a clean machine and effective manual prescrapping are essential in any type of operation.

Economics Laboratory's recommendation for the 140°F sanitizing rinse temperature is based on experience which shows that this provides an acceptable drying time not achieved at the standard 75°F. For health care this higher temperature offers an added margin of safety. The recommendation of 140°F inlet water insures that the tank water will remain above the minimum required by the FDA Model Food Service Sanitation Ordinance and the NSF standards.

Microbiological Efficacy

Economics Laboratory, Inc. has spent nearly a year evaluating the microbial efficacy of the low temperature - chemical sanitizing warewashing systems both in the laboratory and in the field. The data show that the Public Health Standards of cleanliness and sanitation are met.

High levels of microbiological contamination with tenacious food soils (beef stew, animal fat, potato, macaroni and cheese, orange and tomato juice, cocao, milk, teat and lipstick) were used in the controlled laboratory tests in order to present the systems with as rigid a challenge as possible. A heavy inoculum of a pathogenic organism was used in conjunction with the food soils to provide a challenge that would exceed any that might be encountered in whatever environment (Exhibits B & C).

Here again the need for proper prescrapping, maintenance of a clean system, etc. was demonstrated. These aspects, however, are the same for conventional systems and procedures/maintenance requirements are covered in the regulations. In health care more than in other areas greater attention to personnel training should be expected.

To obtain comparative data six months of field testing was done using typical food service establishments operating with

their own procedures, equipment and personnel. For the first 2½ months they used conventional high temperature dishmachines. Then low temperature recirculated wash type machines were installed and testing continued for another 4½ months. The data from this study confirms the microbiological effectiveness of the low temperature - chemical sanitizing system (Exhibit D).

Economics Laboratory, Inc. has long shared a major portion of the warewashing detergent products business. Since we are already a leader in warewashing products sales, our evaluation of these systems is not biased by preference. The above summary merely highlights the reasons why this request for a change in the regulations is justified. The documents attached will provide additional information and detail.

We appreciate your cooperation and consideration of our request to allow the use of an additional warewashing system in nursing homes which has been shown to accomplish the necessary task without compromising safety and which offers potential for energy and cost savings.

Sincerely,

ECONOMICS LABORATORY, INC.

Charles R. McDuff

Charles R. McDuff
Director
Government Technical Affairs
Research & Development Dept.

CRM/jc

Enclosure

Forms To Accompany Attorney General's Rules For Rulemaking

EXHIBIT J

Exhibit J: Petition for Adoption.
Suspension or Repeal of Rule

(OFFICIAL USE ONLY)

PROPOSED RULE
AMENDMENT

MINNESOTA DEPARTMENT OF
Health

DATE RECEIVED
DATE RESPONDED TO _____
ACTION TAKEN _____
DATE _____

NAME C. R. McDuff, Director, Government Technical Affairs

GROUP REPRESENTED OR TITLE Economics Laboratory, Inc.

ADDRESS Osborn Building, St. Paul, MN 55102

I hereby request that the Department named above:

(Check one)

X Adopt a new rule governing MHD 82 (7)(bb) - Dishwashing (Hospitals)

___ Suspend Rule _____

___ Repeal Rule _____

Insert here the new rule or rule change, with the exact wording proposed. Present wording of the rule is to be shown, with all wording that is to be deleted to be shown with a line drawn through the words. All proposed new wording is to be underscored.

See attachment I (h) To add to (bb) - Machine Washing with low temperature - chemical sanitizing machines.

(Use additional pages if necessary)

State here in as much detail and as completely as possible the reasons for your request, as the department will use as part of the basis for its decision the explanation or reasons given for your request.

1. Reduced energy consumption
2. Cost savings
3. Microbial efficacy - Clean & Sanitary Dishes
4. Compliance with standards

(additional space if necessary) See attachment II (h)

Hospital Regulations

Economics Laboratory, Inc. requests a change in part MHD 82 Rules and Regulations for Hospital - "Food Service & Food Sanitation", section (7) "Dishwashing Facilities & Methods", (bb) "Mechanical" to add the following:

Chemical Sanitizing Dishmachines: Machines (single-tank, stationary-1 & 2 rack, door-type machines) using chemicals for sanitization may be used: Provided that:

(A) The temperature of the wash water shall not be less than 140°F. measured at the fill line.

(B) The Wash water shall be kept clean.

(C) Chemicals added for sanitization purposes shall be automatically dispensed.

(D) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturer's specifications for time and concentration.

(E) The chemical sanitizing rinse water temperature shall not be less than 140°F. measured at the fill line.

(F) Chemical sanitizers used shall be aqueous solutions which will provide not less than 50 ppm nor more than 200 ppm available chlorine (21 CFR 178.1010) and be EPA registered for this use.

(G) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Each machine shall be equipped with an empty drum warning signal for the sanitizer.

If the same person handles both soiled and clean dishes, he shall wash his hands between operations. Dishes and utensils shall be air dried.

Exhibit A

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MAR 28 1979

Executive Officer
Minn. Dept. of Health

ECONOMICS LABORATORY, INC.
OSBORN BUILDING, ST. PAUL, MINNESOTA 55102

RESEARCH AND DEVELOPMENT DEPARTMENT

TELEPHONE: (612) 451-5600

File: 1821
Date: 11-10-78

Series: 6C
Report: 161

CONFIDENTIAL
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Warewashing Cost Comparison
Conventional vs Low Temperature

By

R. D. LaRock

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I ABSTRACT

As a leader in the field of Institutional Warewashing, it is incumbent upon Ecomonics Laboratory, Inc., to be fully informed on all aspects of new developments in this field. The upsurge in popularity of Low Temperature Chemical Sanitizing Warewashing Systems is such a development. Operating cost savings through reduced energy consumption has been a basic claim of proponents of these low temperature systems. This study was conducted to determine the extent to which this claim is valid.

Information on which to base this determination was gathered in a dozen existing accounts through careful monitoring of 1) energy, 2) utility, and 3) chemical product consumption.

Test results show that cost savings are indeed possible. Energy cost reductions are sufficient to offset the cost of the additional chemical sanitizing product, and to provide a net operating cost reduction equal to approximately 10% of the cost of the total energy used in the warewashing operation.

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II Introduction

III Test Procedures and Results

- a. Test Procedures
- b. Results

IV Summary

V Conclusion

VI Appendix

- a. Table I
- b. Table II
- c. Table III

II INTRODUCTION

Systems utilizing the Low Temperature/Chemical Sanitization approach to warewashing have gained increasing acceptance over the past few years. These systems now represent a significant chare of the warewashing market. A primary factor in this growth has been the claim of substantially reduced warewashing costs through reduced energy consumption. As a recognized leader in the field of warewashing, it is essential that Economics Laboratory have complete, accurate and current information on all aspects of this development, including how much energy can be saved, the areas in which these energy savings can be made, and the net cost reduction that might be realized through adoption of a low temperature warewashing system.

To generate the data necessary to derive this information, a total of twelve (12) warewashing operations were monitored; seven (7) conventional door-type machines, four (4) batch type low temperature machines, and one (1) second generation low temperature machine. Included in these twelve operations is one direct replacement situation, in which the account replaced their conventional door-type machine with a second generation low temperature machine; this gave us the opportunity to make a direct comparison study.

In all operational studies, energy/utilities consumption was metered, chemical products used were inventoried and dishmachine production was determined by electric counters. Man-hour labor estimates were furnished by the account managers.

Installation of the metering/counting devices was carried out by R. D. LaRock, with assistance from J. D. Addison, J. L. Beecher, and C. H. Irwin, as required. Weekly meter readings and inventory checks were taken by R. D. LaRock for eleven of the studies, with J. D. Addison taking over this function for the last study, which involved the second generation low temperature machine. Microbiological sampling was carried out in several of the accounts by Linda Crowell, Bertha Givens, and Beverly LaClair. A separate report by Linda Crowell, covering this share of the testing has been written. (See File Report No. 1810 dated 9/14/78).

Northern States Power Company furnished the electric watt hour meters needed for this study and also gave us invaluable assistance regarding energy calculations, rate structures, meter requirements and metering wiring procedures. Mr. Robert Burg, Energy Consultant, and Mr. Virgil Ward, Meter Repair Section Foreman, were our primary contacts at NSP.

III TEST PROCEDURES AND RESULTS

This study was carried out over a period of nearly two (2) years. The length of study in a given account ranged from two(2) weeks to three (3) months. The actual time required depended upon a number of account variables, including: personnel changes, equipment malfunctions and ordering/delivery problems. In short, anything that would affect the normal functioning of the warewashing operation. The data presented in this report was collected during periods of "normal" operation.

A. Test Procedures

Electrical energy consumption was determined via the installation of watt-hour meters on the power suply to the:

1. Dishmachine pump and timer/control
2. Washtank heater
3. Final rinse booster heater

Water usage was determined by the installation of water meters installed on:

1. Dishmachine fill line
2. Final rinse line

Sewer charges are based on water consumption.

Natural gas consumption relative to the warewashing operation was determined by a combination of:

1. Metering the water heater gas consumption. In these accounts, the gas meters were installed by Minneapolis Gas Company personnel.

2. Calculations based on water consumption and temperature rise.

Standard conversion factors and formulas for these calculations were verified by Energy Consultants for Northern States Power Company and Minneapolis Gas Company. The determination of energy (gas or electric) consumption through use of these factors/formulas is accepted practice in dealing with water heating considerations.

Physical/operational characteristics recorded in each account, in addition to the metered data described above, include:

1. Incoming (cold) water temperature
2. Primary water heater outlet temperature
3. Booster heater outlet temperature
4. Dishmachine washtank maintained temperature
5. Dishmachine production determined by a counter wired into the washpump motor contactor
6. Product consumption determined through tabulation of weekly inventory checks, including stock on hand and shipments received since last inventory
7. Warewashing labor - the man-hours devoted to the warewashing operations, as estimated by the account manager

B. Test Results

The following tables present 1) the account operating condition/consumption data aas determined by the test procedures described in the previous section, 2) the operating costs derived from these data, and 3) selected/average cost data arranged for side by side comparisons. Accounts are identified by column number. These number designations are consistent throughout the three charts.

Table I - Test Account Physical/Operational Characteristics

Explanations/qualifications concerning certain entries in Table I include the following:

Column 2 - The primary water heater in this account is electric, the only one in the study.

Column 7 - The water heater in this account is a single stage natural gas heater. All hot water used in this account is heated to rinse temperature, 174° in this case. The dishmachine water, both fill and rinse, goes into the machine at this temperature; hence, no primary water heater data is given for this operation. Hot water for general building use is obtained by mixing with cold water through a tempering balve.

Column 8 - This is the same account as Column 7, but this data was recorded after the conversion from a conventional to a low temperature (second generation) dishmachine. After the conversion, the water heater temperature was reduced to 134° F, hence, the energy consumed is recorded as primary water heater data.

Column 9 - This represents another unit of the same chain as Columns 7 - 8. The Energy Mizer dishmachine in use is part of a lease program being test marketed by a local competitor. Because it was a test situation, no inventory of product was maintained at the account, and no product cost information was available. Therefore, only energy and labor data is given for this account.

Table II - Test Account Cost Data

The rates on which the above costs (Table II) are based are: Electricity - 4.5¢ per Kilowatt Hour. Natural Gas - $2.00 per thousand cubic feet. Water - 50¢ per thousand gallons. Sewer - 63¢ per thousand gallons of water used. Chemical Products - current EL pricing (8/78 Pricebook), third weight category (400-999 lb). Labor - $2.50 per hour flat rate. No fringe benefits are included.

Explanation/qualification of certain entries in Table II are as follows:

Column 2 - High primary heater cost is because it is electric. This valve is included in the account totals, but not in the primary heater average cost figure.

Column 7 - The single stage water heater serves as both the booster and primary heater, and so is treated as a booster heater. This situation is unique to this account, of those studied, so this cost is included in the account total but not in the booster heater average cost figure.

Column 8 - The same account as in Column 7, but after the conversion to a second generation low temperature dishmachine. Still a single stage water heater, but at a lower setting (134° F) which is in the primary heater range, hence, the cost is given in that category.

Column 9 - This is the Energy Mizer lease machine - no cost figures available on product consumption.

Column 12 - The chemical products show higher costs in each category than for the other two similar type operations. This is because very high product concentrations were being run, at the time of the study, to overcome the effects of 20 gpg water conditions.

Labor Costs - All labor costs are based on man-hour estimates by the account manger. Colums 1 - 7, representing conventional door type machines, show generally good agreement, with less than a 3¢/rack variation overall. For the batch type low temperature operation (Columns 9 - 12) however, a very wide discrepancy in labor costs is seen. All are higher than the conventional costs and there is nearly a 9¢ per rack variation in cost within this group. This can only be attributed to differences in operational conditions within the account, primarily the production per day. Within this group (Columns 9 - 12) there is a general inverse relationship between production and cost; i.e., higher production - lower cost. This relationship should logically hold for all operations, subject to the modifying influence of other account factors. Bearing this out is the example afforded by the direct replacement "before and after" data reported in Columns 7 and 8.

In this example, the dishmachine was replaced, but all other account factors remained the same; i.e., the same physical dishroom layout, the same dishmachine operators, the same management (personnel and policies), the same dishmachine wash/rinse cycle time, even the same racks. During the 3 month period between the two studies, the number of racks processed per day increased by 36, due to normal summer business increase. Man-hours increased by 1 hour per day to handle the extra load, but the actual labor cost per rack decreased by 0.47¢. The only explanation for this is that the increased volume resulted in better overall utilization of the dishmachine operator's time.

Columns 9 and 10 represent the two highest production batch type low temperature operations. The labor costs shown for these two accounts are very close to each other, and average 15.29¢/rack. This is 4.32¢/rack higher than the conventional machine average, but is substantially less than (5.56¢/rack) the cost for the next lower volume operation (Column 11) and dramatically below (8.85¢/rack) the cost in Column 12, the lowest volume operation.

NOTE: Regarding the labor cost shown in Column 12, this figure of 24.14¢/rack represents a 2 minute cycle - single rack machine. Certainly, this must be considered as a part of the reason for the high labor cost. However, we must also consider that five (5) man-hours per day are spent on the warewashing operation, and only 52 racks are washed during that time. This means that only ten (10) racks are washed per hour, or one rack every six minutes, which is certainly far below the production capability of the machine. Therefore, the longer wash cycle would seem to have a minimal effect on the labor cost in this operation, leaving the low production volume as the main factor in the high labor cost.

Table III - Cost Comparisons - Based on Machine Type

This table presents the averages of the conventional and batch type low temperature operations in a side-by-side format for easy comparison. Likewise, the cost data from the two studies conducted in the machine replacement phase of the project is presented in the same side-by-side format. Exceptions and/or qualifications to these figures have been discussed relative to Tables I and II.

IV SUMMARY

A total of twelve (12) warewashing operations were studied. Of these, there were seven (7) conventional door type, four (4) batch type low temperature, and one (1) second generation low temperature dishmachine operations.

All accounts were operated independently of the study; i.e., account conditions, product consumption and result levels continued to be determined by the Account Manager and the E.L. Territory Manager.

Test Account Data recorded included:

1. Energy Consumption - natural gas and electricity
2. Utilities - water and sewer
3. Chemical Product used - detergent, rinse additive and sanitizer
4. Labor - man-hours attributable to warewashing only

The raw data collected is summarized in Table I. Table II contains the overall cost information derived from the test data. Average cost, arranged for comparison, is presented in Table III.

Exceptions and/or Qualifications to this information are discussed in detail following Tables I and II.

V CONCLUSIONS

Based on comparison with the conventional door type operation, energy costs/consumption will indeed be reduced by adoption of a low temperature warewashing system, either batch type or second generation.

Utilities consumption/cost will increase with either low temperature system; 40% with the batch type and 17% with the second generation system.

Chemical product costs for second generation machines will be equal to or slightly less than chemical costs for a similar conventional operation.

Labor costs for second generation low temperature warewashing operations will approximately equal those of comparable conventional system.

Test results indicate that labor costs for batch type operations will increase, as compared to conventional operation costs, but inconsistencies in the accumulated data preclude drawing a firm percentage estimate.

Overall costs, excluding labor, are significantly less for both low temperature systems, i.e., energy savings are large enough to offset the cost of the extra product and higher utilities ang give a net savings of nearly 10%.

Respectfully submitted,

Richard D. LaRock

RDL:cg

	1	2	3	4	5	6	7	8	9	10	11	12
MACHINE MAKE	HOBART	HOBART	HOBART	HOBART	CHAMP	CHAMP	HOBART	CHAMP	ENERGY	STERO	STERO	STERO
MACHINE MODEL	AM-9	AM-9	AM-9	AM-11	KB-1	KB-1	AM-9	FW-60	MIZER	SC-20-2	SC-20-2	SC-20-1
Temperatures (^{o}F)												
Cold Water	40	48	41	41	39	45	37	39	40	50	42	42
Primary Hot	149	161	161	158	154	148	---	134	138	155	158	155
Final Rinse	188	185	185	184	185	184	174	---	---	---	---	---
Washtank	148	153	155	157	158	155	161	120	---	---	---	---
Water Used (gal)												
Fill	952	653	1,765	2,467	1,283	2,910	6,310	-----	-----	-----	-----	-----
Rinse	2,848	2,031	4,152	3,145	3,724	5,426	17,962	39,600	12,100	7,788	5,385	2,796
Natural Gas (ft.^{3})												
Primary Heater	5,470	-----	9,380	8,670	7,590	10,563	------	46,470	16,300	10,790	8,246	4,170
Booster Heater	-----	-----	-----	-----	-----	------	43,893	------	------	------	-----	-----
Electricity (KWHr)												
Primary Heater	-----	988.8	-----	-----	-----	-----	------	------	------	------	-------	------
Booster Heater	432.7	250.2	276.3	187.6	563.2	1,752.0	-------	--------	------	------	-------	------
Tank Heater	305.4	64.0	227.7	567.9	737.2	1,020.5	2,564.4	788.6	-------	------	-------	------
Pump & Control	20.6	17.2	50.7	36.6	30.7	55.2	135.0	334.4	126.4	78.5	57.8	30.0
Chemical Products												
Detergent (lb)	74	69	98	86	116	228	360	366	-----	----	---	---
Detergent (gal)	----	----	----	----	-----	-----	-----	-----	-----	6.7	6.6	4.0
Rinse Add. (gal)	1.4	0.5	0.9	0.7	1.2	1.4	2.3	3.5	-----	1.3	0.8	0.6
Sanitizer (gal)	----	----	-----	-----	-----	-----	-----	18.7	-----	4.3	4.4	3.2
Total Man Hours	82	55	120	126	126	216	546	728	294	160	168	90
Total Racks Washed	1,984	1,451	2,750	2,714	2,865	4,418	12,147	16,898	4,840	2,596	2,014	932
Racks Per Day	283	207	393	388	205	210	289	325	231	260	144	52

WAREWASHING COST COMPARISON : CONVENTIONAL VERSUS LOW TEMPERATURE

COST CATEGORY	CONVENTIONAL								LOW TEMPERATURE					
	Door Type Machines								2nd Gen.	Batch Type Machines				
	1	2	3	4	5	6	7	Avg	8	9	10	11	12	Avg
Primary Heater	0.54	3.07	0.68	0.64	0.53	0.48	-	0.57	0.55	0.67	0.83	0.82	0.88	0.80
Booster Heater	0.98	0.78	0.45	0.32	0.89	1.79	0.72	0.87	-	-	-	-	-	-
Tank Heater	0.70	0.20	0.37	0.94	1.16	1.04	0.95	0.76	0.21	-	-	-	-	-
Pump and Control	0.05	0.07	0.08	0.06	0.05	0.06	0.05	0.06	0.09	0.12	0.13	0.12	0.14	0.13
ENERGY TOTAL	2.27	4.12	1.58	1.96	2.63	3.37	1.72	2.26	0.85	0.79	0.96	0.94	1.02	0.93
Water	0.10	0.09	0.11	0.10	0.09	0.09	0.10	0.10	.12	0.13	0.15	0.13	0.15	0.14
Sewer	0.13	0.11	0.14	0.13	0.11	0.11	0.13	0.13	0.15	0.16	0.19	0.16	0.19	0.18
UTILITIES TOTAL	0.23	0.20	0.25	0.23	0.20	0.20	0.23	0.23	0.27	0.29	0.34	0.29	0.34	0.32
Detergent	1.94	2.47	1.85	1.57	2.01	2.56	1.82	2.03	1.31	-	1.50	1.91	2.50	1.97
Rinse Addict.	1.22	0.60	0.57	0.45	0.72	0.55	0.33	0.63	0.34	-	0.71	0.56	0.91	0.73
Sanitizer	-	-	-	-	-	-	-	-	0.33	-	0.50	0.67	1.05	0.74
CHEMICAL TOTAL	3.16	3.07	2.42	2.02	2.73	3.11	2.15	2.66	1.98	-	2.71	3.14	4.46	3.44
SUB-TOTAL	5.66	7.39	4.25	4.21	5.56	6.68	4.10	5.15	3.10	-	4.01	4.37	5.82	4.69
LABOR	10.33	9.48	10.91	11.61	10.99	12.22	11.24	10.97	10.77	15.18	15.41	20.85	24.14	18.90
COMBINED TOTAL	15.99	16.87	15.16	15.82	16.55	18.90	15.34	16.12	13.87	-	19.42	25.22	29.96	23.59

TABLE III

COST COMPARISONS - BASED ON MACHINE TYPE

COST CATEGORIES	AVERAGE COSTS				DIRECT MACHINE REPLACEMENT			
	Conv.	Batch	Change (Based on Conv)		Conv	Second Gen.	Change)Based on Conv)	
	1 - 7	9 - 12	¢/Rack	%	7	8	¢/Rack	%
Primary Heater (Natural Gas Only)	0.57	0.80	--	--	--	0.55	--	--
Booster Heater (Electric Only)	0.87	--	--	--	0.72	--	--	--
Tank Heater	0.76	--	--	--	0.95	0.21	--	--
Pump and Control	0.06	0.13	--	--	0.05	0.09	--	--
ENERGY TOTAL	2.26	0.93	-1.33	-58.8	1.72	0.85	-0.87	-50.6
Water	0.10	0.14	--	--	0.10	0.12	--	--
Sewer	0.13	0.18	--	--	0.13	0.15	--	--
UTILITIES TOTAL	0.23	0.32	+0.09	+39.1	0.23	0.27	+0.04	+17.4
Detergent	2.03	1.97	--	--	1.82	1.31	--	--
Rinse Additive	0.63	0.73	--	--	0.33	0.34	--	--
Sanitizer	--	0.74	--	--	--	0.33	--	--
CHEMICAL TOTAL	2.66	3.44	+0.78	+29.3	2.15	1.98	-0.17	- 7.9
SUB-TOTAL	5.15	4.69	-0.46	-8.9	4.10	3.10	-1.00	-24.4
LABOR	10.97	18.90	+7.93	+72.3	11.24	10.77	-0.47	-4.2
COMBINED TOTAL	16.12	23.59	+7.47	+46.3	15.34	13.87	-1.47	-9.6

Exhibit B

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Executive Officer
Minn. Dept. of Health

ECONOMICS LABORATORY, INC.
OSBORN BUILDING, ST. PAUL, MINNESOTA 55102

RESEARCH AND DEVELOPMENT DEPARTMENT

TELEPHONE: (612) 451-5600

File: 1746
Date: 8-12-77

Series: 6C
Report: 154

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Sanitizing Efficiency Of Low Temperature Warewashing Systems

By

L. L. Crowell

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ABSTRACT

As a result of the increased use of low temperature warewashing systems in commercial establishments studies were initiated to evaluate the sanitizing capabilities of these machines in order to respond effectively to the concerns of the public health departments.

The evaluation of the low temperature dishmachines both under controlled conditions in the laboratory and under actual use conditions in the field demonstrated that sanitization of contaminated eating utensils is achieved by the presence of 50 ppm. available chlorine within the final rinse in the system. Laboratory data showed that all bacterial counts were well within the public health standard of 100 colony forming units per utensil except in those situations where gross soil particles were not removed during the washing process.

Microbiological evaluations on utensils processed by low temperature dishmachines currently being used in the Minnesota area indicate that Public Health standards of cleanliness and sanitation are being met.

INTRODUCTION

With the increasing use of low temperature dishmachines in institutional and commercial establishments, questions are being raised as to their ability to clean and sanitize. Various health agencies are reluctant to accept chemical sanitation in lieu of a 180°F final rinse. Due to a lack of sufficient documentation on low temperature chemical sanitation, additional in-house and field testing was needed to enable us to accurately respond to questions on cleaning and sanitizing performance.

A two phase project was established to accomplish the above. The first phase was the development of microbiological efficacy data on the sanitizing capabilities of the low temperature dishmachine process under realistic, challenging use conditions. Testing was done in conjunction with the "Cleaning Efficiency Studies" conducted by the Institutional Product Development Laboratory for the purpose of evaluating various operational conditions and establishing the limits within which acceptable cleaning results could be achieved. Having established these parameters, Microbiological Services proceeded to evaluate the sanitizing effectiveness under various soil conditions.

The second phase of this project was the microbiological evaluation of utensils processed by low temperature dishmachines currently in operation in the field (Minnesota area) and on utensils processed by conventional high temperature dishmachines. The purpose was to provide data documenting the sanitary results of low temperature dishwashing and second to serve as a basis for comparison with the sanitation results from conventional machines.

DISCUSSION

Improperly cleaned and sanitized dishes have been found to carry microorganisms which are indicative of potential disease hazard. Although there is little direct evidence that eating utensils are carriers of pathogenic organisms, it is, however, good public health practice to eliminate any potential health hazard by sanitizing dishes properly. The United States Public Health Service has set a standard of not more than 100 organisms per eight square inches of dish surface, a standard both convenient and attainable. Bacterial counts in excess of 100 colonies per utensil surface sampled do not necessarily indicate a potential disease hazard, but when such counts are below 100 it is evident that dishwashing procedures are satisfactory and that dish contaminates have been removed.

Extensive documentation exists on the cleaning and sanitizing performance of conventional high temperature dishwashing machines with a final rinse of 180°F. Unfortunately, very little data is available which demonstrates the cleaning and sanitizing capabilities of the new low temperature dishmachines.

Therefore, studies were initiated to establish the compliance of these chemical sanitizing dishmachines, which utilize an accepted and approved sanitizing agent (50 ppm available Cl_2), with the Public Health standards of cleanliness and sanitation.

It is generally recognized that effective soil removal is a prerequisite to chemical sanitation processes. Accordingly, the Institutional Product Development Group developed a designed experiment regarding the operational conditions affecting cleaning. In conjunction with these cleaning tests, inoculated soils were incorporated to measure the sanitizing efficacy of the system. Major considerations in sanitization by the low-temperature dishmachines must include:

1. Adequate soil removal;
2. Availability of the sanitizing agent, $NaOCl_2$, in the presence of detergent, soil load, or a combination thereof;
3. Bacterial harboring potential of organic and inorganic films.

A separate report on the cleaning efficiency study has been prepared by J. Copeland, with details of the test design and results of such tests to be found therein. (IPDTP 39).

This report shall be limited to the microbiological aspect of the study, and is presented in two parts: Laboratory Evaluations, and Field Evaluations.

Results of the Cleaning Efficiency Study indicated the necessity of considering the following variables, which are listed in order of significance:

1. Temperature: the most significant variable affecting cleaning results. Small increases in temperature improved these results, especially in the removal of fats.

2. Water Hardness: Results which would be considered commercially acceptable deteriorated with the repeated cycling of dishware. Eco-Kleen is designed to work in water ranging from zero to five (0 - 5) grains hardness; beyond this limit, water hardness becomes a significant factor in obtaining acceptable or desired results, due to deposition of mineral deposits on utensils. A secondary effect then comes into play: inorganic films can act as carriers to which organic matter can adhere, thus making a utensil more difficult to clean.

3. Soils: How the soil is prescraped takes precedence over the soil type. Wet prescraping removes the greater amount of gross soil, thus less remains to be introduced into the machine; that soil which remains has been wetted, facilitating its removal in the wash cycle.

   Dry prescraping leaves a greater amount of soil residue to be introduced into the wash water, and such residue, having not been prewetted, has greater adhesion to the utensil.

LABORATORY EVALUATION
Equipment and Materials

A Champion low temperature dishmachine (Champion CKW-1) was used in a majority of the laboratory studies. Utensils used as testing media were glasses, china, and melamine plates and cups. Food soil preparation and application methods used are described in the report of J. Copeland, as hereinbefore mentioned.

Testing procedure under a given set of conditions involved the application of suspended test organisms to the utensil or, in the case of liquid food soils, to the food. A determination of the number of surviving organisms per utensil after processin g was made according to the standard swab-rinse technique. Samples of wash water and rinse water were taken in each test run.

Test Conditions

Water temperatures in all laboratory tests were from 120°F to 140°F. Food soils used in Experiments I, II, and III were beef stew, animal fat (melted), potatoes, macaroni and cheese, fresh whole milk, orange juice, tomato juice, tea and cocoa. Soil loads ranged from heavy to light, as defined in the report of J. Copeland.

A standard detergent concentration was used (.1%), and runs were also made in the absence of detergent. Sanitizing agent used was $NaOCl_2$ (50 ppm available chlorine).

Experiments I, II, III and IV were performed in Saint Paul City water, using dishmachine's standard operating procedure.

Test Organism

The test organism selected for this work was a twenty-four culture of Staphylococcus aureus (ATCC 6538), maintained in Tryptocase Soy Broth. Selection of this organism was based upon: (1) its public health significance; (2) its high resistance to conditions of heat and drying, and, (3) its prevalence on improperly sanitized utensils.

Because of the ten liter water volume in the wash cycle, an extremely high inoculation of the system was made. Based on preliminary studies, we were able to determine that the inoculation of each utensil with 10^8 cells would consistently yield a recoverable 10^5 organisms per milliliter of wash-water.

Contamination Procedure

Procedure was as follows: In the case of dinner plates, .5 milliliter of the test culture suspension was pipetted onto each plate. The organisms were spread uniformly over approximately 18 square inches on the center of each plate with the aid of a rubber policeman, and air dried for one hour at room temperature. Food soil, cooled to 45 C , was then applied in a like manner. After one hour, dishes were prescraped and processed.

Liquid soils were inoculated with the culture suspension of 10^8 cells per milliliter. Test glasses were then filled with respective inoculated soils. In pouring off excess soil, glasses were rotated to ensure coating of all inner surfaces. Glasses air dried one hour before processing.

Bacterial Recovery Procedure

Immediately following dishmachine processing, the racks were removed and swab samples were taken of each inoculated utensil. The inoculated/soiled area of each plate and the rim and two-thirds of the inner surface of each glass were swabbed. Swabs were then returned to vials containing 5 milliliters of thiosulfate buffer and transported to the laboratory for processing. Each vial was then vortexed for 30 seconds and the entire solution was plated on Tryptocase Glucose Extract Agar. All plates were incubated at 37°C for 48 hours. Bacteria counts for the same are reported as total number of organisms isolated per utensil.

Microbial determinations were also made on the wash and rinse water samples collected from each run.

EXPERIMENT I

As a result of the cleaning efficiency studies, parameters were defined for various operating conditions, which represent situations actually encountered in the field. The purpose of this experiment was to determine whether 50 ppm Cl_2 would adequately sanitize highly contaminated, food soiled dishware under such use conditions.

The equipment, media, test conditions, and organisms, and contamination and recovery procedures were as previously described.

Results: The results of these tests are shown in Table I, A and B. Data clearly demonstrates that sanitization of contaminated utensils is achieved by the presence of 50 ppm available chlorine within the system. Except in those situations where gross soil particles were sampled, all bacterial counts were well within the standards of accepta-

bility, of 100 colonies per utensil, as set by the United States Public Health Service.

As evidenced by the bacterial counts of the wash and rinse waters, residual carryover of chlorine into the following wash cycle drastically reduced the inoculum count of that cycle.

EXPERIMENT II

The object of this test was to determine whether increasing the concentration of the detergent would aid in sanitization. Inoculating and soiling procedures were as hereinbefore described, with the following exceptions: (1) Poor prescraping procedures (heavy soil load); (2) Detergent concentrations of 0%, 1.%, and .4%; (3) Water temperatures of 130°F; (4) Cl_2 concentration of 0 ppm.

Results: As reported in Table II, data demonstrate that increasing the detergent concentration to .4% does not aid in the sanitization of dishware even though cleaning results were vastly improved (no filming visually evident).

EXPERIMENT III

"Clean" (non-filmed) glasses and "Filmed" glasses were inoculated and soiled with milk according to procedures used in Experiment I. Variables in the test included temperature, detergent concentrations and chlorine concentrations. Uninoculated "Clean" and "filmed" glasses were also included in test runs without chlorine to determine the degree of microbial deposition onto each surface type.

Results: As reported in Table III, the data indicate that sanitization of inoculated glasses was accomplished when chlorine was present in the system. In all instances the number of bacteria recovered from the "filmed" glasses were comparable to the number recovered from the "Clean" or non-filmed glasses, thus indicating the ability of chlorine to penetrate an inorganic film.

EXPERIMENT IV

In order to truly challenge the capability of the low-temperature dishmachine to clean and sanitize, rims of glasses were inoculated with a broth culture of Staphylococcus aureus, allowed to air dry, and then coated with a heavy layer of lipstick prior to processing. Other procedures and conditions were as described in Experiment I, with the following exceptions:

(1) Temperature 130°F; (2) Detergent concentrations of 0%, .1%; (3) Cl_2 concentrations of 0 ppm, 50 ppm; (4) No food soils used.

Results: Indicated that subject dishmachine at 130°F is capable of removing lipstick-type base soils. Residual bacteria, however, are adequately reduced only in the presence of 50 ppm Cl_2.

EXPERIMENT V

The purpose of this experiment was to evaluate the cleaning and sanitizing system of the Stero Low Temperature Dishmachine, utilizing a new hard water detergent in combination with 50 ppm chlorine. The inoculation and soiling procedures were as hereinbefore described with the following exceptions: (1) Melamine plates and cups included in the test; (2) Poor scraping procedures used throughout; (3) Soft and hard water used.

Results: The microbiological results of these tests are shown in Tables V,A and B. Data clearly demonstrates that sanitization of both the china and melamine plates and cups in soft and hard water was achieved by the presence of 50 ppm available chlorine within the system, except where gross soil was present.

PHASE II: Field Evaluations

To evaluate the sanitizing efficacy of the low-temperature dishmachine under actual commercial use conditions, microbiological swab tests were made at four accounts currently using the Stero low-temperature dishmachine. A minimum of two calls were made at each of these accounts, with forty to fifty swab samples taken per call.

Operating conditions were also recorded, including wash and rinse temperatures, Cl_2 concentrations, and general comments concerning machine performance.

As indicated by the data reported in Table IV the microbiologicla results demonstrate that in 9 out of 10 samplings covering 4 separate accounts sanitization criteria was met.

Comparable microbiological evaluations were conducted on conventional high-temperature dishmachines within the Twin

City area. This study involved evaluation of 38 such dishmachines. Plate counts were performed on swab samples taken from randomly selected utensils immediately following processing. Approximately fifteen swab samples of plates, cups, glasses, forks and spoons were taken per machine. Results of these tests will be found in Table V.

Of the machines tested, sixty-three per cent (63%/24 machines) demonstrated effective bactericidal treatment of all utensils examined: the average plate count for each type of utensil was below the 100 colony allowance. The remaining fourteen machines (37%) produced two or more types of processed utensils exceeding the 100 colony limit.

CONCLUSION

The sanitizing capability of the low temperature dishmachine has been demonstrated both under controlled laboratory conditions and under actual field use conditions.

In all laboratory tests sanitization of contaminated eating utensils was achieved by the presence of 50 ppm available chlorine within the final rinse. All bacterial counts were well within the public health standard of 100 colony forming units per utensil sampled except in those situations where gross soil particles were not removed during the washing process.

Microbiological results of swab samples taken on utensils processed by low temperature dishmachines within the Minnesota area show that Public Health Standards of cleanliness and sanitation are met.

Comparative evaluation of utensils processed by conventional high temperature dishmachines indicated that out of the 38 dishmachines tested 24 demonstrated effective bactericidal treatment of all utensils samples. However, only 19 (50%) met the final rinse water temperature requirement of 180°F.

TABLE I A

Good Prescraping Conditions (Light Soil Load)

Operational Conditions		Surviving Organisms					
		Wash H_2O/ml	Rinse H_2O/ml	Soil	Swab #1		Swab #2
Run I							
Temp.	120°F	4.0×10^3	2×10^2	Beef Stew	158		2
Detergent	0			Animal Fat	405		103
Cl_2 Conc.	0 ppm			Macaroni/Cheese	150		415
Jet Dry	0			Potato	TNTC(x)		-
		8.0×10^2	8.0×10^1	Coco	27		24
				Milk	10		21
				Orange Juice	46		22
				Tea	9		30
				Tomato Juice	17		22
				Uninoculated Glass	5	17	16
Run II							
Temp.	120°F	0	0	Beef Stew	7		0
Detergent	.1%			Animal Fat	125		20
Cl_2 Conc.	50 ppm			Macaroni	0		0
Jet Dry	200 ppm			Potato	0		1800(x)
				Coco	0		0
				Milk	0		0
				Orange Juice	0		0
				Tea	0		0
				Tomato	0		0
				Uninoculated	0	0	0
Run III							
Temp.	130°F	0	0	Beef Stew	0		0
Detergent	.1%			Animal Fat	0		0
Cl_2 Conc.	50 ppm			Macaroni	0		0
Jet Dry	200 ppm			Potato	2(x)		115(x)
		3	0	Coco	0		0
				Milk	0		0
				Orange Juice	35		0
				Tea	0		0
				Tomato Juice	0		0
				Uninoculated	0	0	0

Operational Conditions		Wash H_2O/ml	Rinse H_2O/ml	Soil	Swab #1		Swab #2
Run IV							
Temp.	140°F	1.5×10^3	4	Beef Stew	0		0
Detergent	0			Animal Fat	0		3
Cl_2 Conc.	0 ppm			Macaroni	1		TNTC (x)
Jet Dry	0			Potato	1		0
		2.2×10^3	--	Coco	4		3
				Milk	1		1
				Orange Juice	1		2
				Tea	1		1
				Tomato	3		70
				Uninoculated	0	0	0
Run V							
Temp.	140°F	1	0	Beef	126 x		0
Detergent	.1%			Animal Fat	0		0
Cl_2 Conc.	50 ppm			Macaroni	5		0
Jet Dry	200 ppm			Potato	1		0
		0	0	Coco	0		0
				Milk	0		0
				Orange Juice	0		0
				Tea	0		0
				Tomato Juice	0		0
				Uninoculated	0	0	0

Poor Prescraping Conditions (Heavy Soil Load)

Operational Conditions		Surviving Organisms: Wash H_2O/ml	Rinse H_2O/ml	Soil	Swab #1		Swab #2
Run I							
Temp.	120°F	8.5×10^4	8.2×10^3	Beef Stew	550		1800
Detergent	0%			Animal Fat	156		128
Cl_2 Conc.	0 ppm			Macaroni/Cheese	TNTC(x)		TNTC(x)
Jet Dry	0 ppm			Potato	TNTC(x)		TNTC(x)
		1.0×10^4	8×10^2	Coco	88		90
				Milk	195		94
				Orange Juice	148		130
				Tea	95		127
				Tomato Juice	209		95
				Uninoculated Glass	50	35	40
Run II							
Temp.	120°F	0	0	Beef Stew	4		4
Detergent	.1%			Animal Fat	1		90
Cl_2 Conc.	50 ppm			Macaroni/Cheese	5		TNTC(x)
Jet Dry	200 ppm			Potato	TNTC(x)		TNTC(x)
		0	0	Coco	0		2
				Milk	2		0
				Orange Juice	0		1
				Tea	0		0
				Tomato Juice	2		0
				Uninoculated Glass	0	0	0
Run III							
Temp.	130°F	0	0	Beef Stew	25		3
Detergent	.1%			Animal Fat	2		76
Cl_2 Conc.	50 ppm			Macaroni/Cheese	280 x		82
Jet Dry	200 ppm			Potato	TNTC(x)		TNTC(x)
		0	0	Coco	0		0
				Milk	0		0
				Orange Juice	0		0
				Tea	0		0
				Tomato Juice	0		0
				Uninoculated	0	0	0

Operational Conditions		Wash H_2O/ml	Rinse H_2O/ml	Soil	Swab #1		Swab #2
Run IV							
Temp.	140°F	7.5×10^3	2.0×10^2	Beef Stew	TNTC(x)		290
Detergent	0%			Animal Fat	53		TNTC
Cl_2 Conc.	0 ppm			Macaroni/Cheese	TNTC		600
Jet Dry	0 ppm			Potato	TNTC		500(x)
		30	0	Coco	25		15
				Milk	13		38
				Orange Juice	45		10
				Tea	24		14
				Tomato Juice	25		15
				Uninoculated	12	17	9
Run V							
Temp.	140°F	0	0	Beef Stew	475		370
Detergent	.1%			Animal Fat	0		0
Cl_2 Conc.	50 ppm			Macaroni/Cheese	21		0
Jet Dry	200 ppm			Potato	800(x)		1500(x)
				Coco	0		0
				Milk	0		0
				Orange Juice	0		0
				Tea	0		0
				Tomato Juice	0		0
				Uninoculated	0	0	0

TABLE II

Poor Prescraping Conditions

Increased Detergent Concentration

Operational Conditions		Soil	Surviving Organisms Swab #1	Swab #2	Wash H_2O/ml	Rinse H_2O/ml
Run I						
Temp.	130°F	Beef Stew	350	340	5.2×10^4	4.0×10^3
Detergent	0	Animal Fat	60	104		
Cl_2 Conc.	0 ppm	Macaroni	780	1480		
		Potato	$460_{(x)}$	$TNTC_{(x)}$ (3000)		
Run II						
Temp.	130°F	Beef Stew	420	1206	3.6×10^4	4.5×10^3
Detergent	.1%	Animal Fat	50	140		
Cl_2 Conc.	0 ppm	Macaroni	208	115		
		Potato	$TNTC_{(x)}$ (2000)	TNTC		
Run III						
Temp.	130°F	Beef Stew	210	240	10^4	1.7×10^3
Detergent	.4%	Animal Fat	70	22		
Cl_2	0 ppm	Macaroni	0	3		
		Potato	$TNTC_{(x)}$	$TNTC_{(x)}$		

Uninoculated Potato Plate = Spreader, bacillus type.
Very few Staph.

TABLE III

Protein Soil (Milk)

Operational Conditions				Surviving Organisms				
		Cl_2 Conc (ppm)		Mean Swab Count		Wash	Rinse	Uninoculat
Temperature	Detergent	Wash H_2O	Rinse H_2O	"Clean"	"Filmed"	H_2O/ml	H_2O/ml	glasses
110 F	0	0	0	$1.6x10^3$	$2.1x10^3$	$2.6x10^4$	$5.2x10^3$	
	.1%	22	23	13	4	1	1	
	.2%	43	41	0	0	0	1	
				$5.5x10^2$*	$3x10^3$*			
120 F	0	0	0	$2.2x10^3$	$2.8x10^3$	$4.4x10^3$	$6.0x10^3$	
	.1%	43	49	6	1	1	2	
	.2%	42	44	2	6	1	1	
				$2.6x10^2$*	$2x10^3$*			
130 F	0	0	0	$9x10^2$	$7.5x10^2$	$6.0x10^3$	$9.0x10^2$	
	.1%	54	54	0	0	1	1	
	.2%	45	45	0	0	0	0	
				$2x10^2$*	$1.2x10^3$*			
140 F	0	0	0	$2.1x10^3$	$2.0x10^3$	$6.6x10^2$	$6.0x10^1$	
	.1%	60	57	0	0	1	16	
	.2%	67	--	$2x10^3$*	$5x10^3$*			

Controls: 1) Each glass inoculated with $1.2x10^8$ cells (approx.)
2) Wash water inoculated with $1.2x10^9$ cells (approx.)
3) Mean count = average of 4 samples

*uninoculated

TABLE IV

Lipstick Films

Operational Conditions			Surviving Organisms		
Temperature	Detergent Conc	Cl_2 Conc (ppm)	Mean Swab Counts	Wash H_2O/ml	Rinse H_2O/ml
130°F	0%	0	TNTC(>4000)	TNTC(>4000)	1.7×10^3
130°F	.1%	0	405	TNTC(>4000)	70
130°F	0% (50 ppm Cl_2 added to wash)	50	<1	0	0
130°F	.1%	50	<1	0	0
130°F	0% (no Cl_2 added to wash)	50	<1	0	0

1) Mean Count - Average bacterial count of 4 swabbed glass

2) Each glass inoculated with approx. 1×10^8 organisms

50% casteroil
50% steric acid

TABLE V A

STERO LOW TEMPERATURE MACHINE
UNDER SOFT WATER CONDITIONS

Operational Conditions		Wash H_2O/ml	Rinse H_2O/ml	Soil	Surviving Organisms: China Swab #1	China Swab #2	Melamine Swab #1	Melamine Swab #2
RUN I								
Temp.	120°F	5.0×10^3	2.5×10^2	Beef Stew	1	3	30(x)	4
Detergent	.05%			Animal Fat	2	9	-	-
Cl_2 conc.	200 ppm			Macaroni	6	8	0	75
Jet Dry	200 ppm			Tomato	14	20		
				Milk	25	5	13	40
				Tea	5	5		
				Clean	6	13	4	
RUN II								
Temp.	120°F	0	0	Beef Stew	1	1	0	0
Detergent	.05%			Animal Fat	0	0	-	-
Cl_2 conc.	50 ppm			Macaroni	37	0	4	0
Jet Dry	200 ppm			Tomato	0	0		
				Milk	0	0	4	1
				Tea	0	0		
				Clean	0	0	0	0
RUN III								
Temp	120°F	5×10^2	9×10^1	Beef Stew	20	75	0	0
Detergent	.02%			Animal fat	3	20	-	-
Cl_2 conc.	0			Macaroni	45	52	4	6
Jet Dry	200 ppm			Tomato	3	5	-	-
				Milk	0	0	9	12
				Tea	1	2	-	-
				Clean	2	6	TNTC	TNTC
RUN IV								
Temp	120°F	0	0	Beef Stew	0	4(x)	0	0
Detergent	.02%			Animal Fat	0	0	-	-
Cl_2 conc.	50 ppm			Macaroni	0	TNTC(x)	0	0
Jet Dry	200 ppm			Tomato	0	0		
				Milk	0	0	0	TNTC(x
				Tea	0	0		
				Clean	0	0	0	0

TABLE V B

STERO LOW TEMPERATURE DISHMACHINE
UNDER HARD WATER CONDITIONS (250 ppm)

OPERATIONAL CONDITIONS		Wash H_2O/ml	Rinse H_2O/ml	SURVIVING ORGANISMS Soil	China Swab #1	China Swab #2	Melamine Swab #1	Melamine Swab #2
RUN I								
Temp.	120°F	$8x10^3$	$2xJ0^2$	Beef Stew	0	1	0	0
Detergent	.05 %			Animal Fat	35	25		
Cl_2 conc.	0 ppm			Macaroni	300	TNTC	0	4
Jet Dry	200 ppm			Tomato Juice	7	11		
				Milk	300	300		
				Tea	2	120	11	9
				Clean	13	25		
RUN II								
Temp.	120°F	0	0	Beef stew	0	6	5	3
Detergent	.05 %			Animal Fat	0	0		
Cl_2 conc.	50 ppm			Macaroni	0	0	0	0
Jet Dry	200 ppm			Tomato Juice	0	0		
				Milk	0	1		
				Tea	0	2	0	0
				Clean	0	0		
RUN III								
Tem.	120°F	$3x10^2$	$2xJ0^1$	Beef Stew	0	0	130(x)	0
Detergent	.02 %			Animal Fat	0	0		
Cl_2 conc.	0			Macaroni	0	0	0	0
Jet Dry	200 ppm			Tomato Juice	0	0		
				Milk	0	1		
				Tea	TNTC	2	16	7
				Clean	5	0		
RUN IV								
Temp.	120°F	0	0	Beef Stew	0	32(x)	0	0
Detergent	.02 %			Animal Fat	0	0		
Cl_2 conc.	50 ppm			Macaroni	0	2	0	300(x)
Jet Dry	200 ppm			Tomato Juice	0	0		
				Milk	0	0		
				Tea	0	0	0	0
				Clean	0	0		

MICROBIOLOGICAL FIELD EVALUATIONS

LOW TEMPERATURE DISHMACHINES

count	Temperature Wash	Rinse	Cl_2 concentration	Utensils sampled	Average bacteria count/ utensil
atross	120	144	78 ppm	7 plates	2
/77)	136	146	82	6 cups	1
	126	144	96	6 forks	< 1
				6 spoons	< 1
	134	145	76	4 plates	1
	136	148	72	6 glasses	< 1
atross	115	138	110	7 plates	1
12/77)	130	145	83	8 glasses	0
	128	139	106	7 cups	2
	136	148	100	5 forks	0
	130	145	105	5 spoons	0
	128	143	112	6 plates	0
inebrook Bowl	110	140	9	7 plates	2
14/77)				5 cups	< 1
	140	156	15	3 plates	1
				5 glasses	4
				2 cups	0
	120	144	15	5 forks	3
				5 spoons	1
inebrook Bowl	144	158	0	2 cups	2
22/77)				3 glasses	< 1
	134	158	0	10 forks	< 1
				10 spoons	1.5
	158	165	0	4 cups	5.0
	150	162	0	4 plates	< 1
	136	150	20	3 plates	9
	134	154	26	2 glasses	0
ainebrook Bowl	140	156	0	5 glasses	14
/7/77)				5 cups	14
				5 plates	10
	142	157	35	5 cups	< 1
				5 plates	< 1
	140	157	63	5 forks	1
				5 spoons	< 1
	148	156	52	3 forks	< 1
				3 spoons	< 1
ur Inns	145	158	74	5 plates	3
/11/77)	145	158	74	5 glasses	0
				5 cups	0
	145	158	74	5 spoons	0
				5 forks	0

	Wash	Rinse		Sampled	utensil
ır Inns	125	19[redacted]	11	5 pla[redacted]	0
/29/77)	147	158	5	3 cups	0
				3 glasses	0
	142	152	1	4 plates	< 1
	132	147	7	3 cups	0
				3 glasses	< 1
	128	148	1	3 forks	1
				3 spoons	< 1
				4 plates	3
	132	150	0	1 cup	TNTC
				4 cups	< 1
				5 glasses	0
ır Inns	130	141	0	8 glasses	7
/29/77)				8 cups	0
	125	143	45	4 plates	< 1
				8 cups	3
	127	143	75	4 forks	0
				7 glasses	0
. Steak (Duluth)	100	122	54	10 plates	15
/16/77)	130	142	47	7 glasses	1
	130	148	52	7 cups	1
	135	148	42	5 forks	60
				7 spoons	2
. Steak (Duluth)	105	132	57	4 cups	88
/13/77)	118	138	56	11 glasses	> 100
	118	138	62	5 plates	50
	122	144	57	1 plate	TNTC
				5 plates	22
	122	148	62	4 forks	8
				4 spoons	9
	122	148	61	4 cups	2

MICROBIOLOGICAL FIELD EVALUATIONS

CONVENTIONAL HIGH TEMPERATURE DISHMACHINES

Establishment	Temperature in °F: Wash	Rinse	Mean Bacterial Count: Plate	Glass	Cup	Fork	Spoon	Knife
1	131	188	0	-	2	-	52	-
2	140	195	0	< 1	-	690	660	-
3	136	158	15	1	-	-	-	-
4	148	190	1	8	-	2	0	-
5	144	164	< 1	5	-	0	4	-
6	150	180	-	8	1	1	< 1	-
7	122	164	-	12	404	4	1	-
8	114	144	1,900	1,006	943	87	688	-
9	120	-	35	500	-	3	92	-
10	156	186	< 1	spreader	spreader	spreader	14	-
11	158	188	0	33 + spr	< 1	0	3	-
12	150	162	0	10	840	-	-	-
13	138	165	> 100	>100	> 100	spreader	0	-
14	158	180	0	> 100	>100	4	>100	-
15	152	185	334	> 100	12	-	> 100	-
16	150	184	< 1	>100	>100	0	0	-
17	178	190	25	> 1	0	-	-	-
18	158	170	47	17	0	220	4	251
19	150	178	-	23	0	0	1	0
20	156	170	3	2	0	0	0	0

21	142	154	0	0	0	0	0	0
22	164	176	>100	4	3	>100	0	0
23	152	184	0	0	0	0	0	0
24	170	170	0	1	0	1	0	0
25	160	182	0	0	0	2	0	0
26	138	175	-	3	1,319	< 1	11	6
27	164	165	-	TNTC	TNTC	TNTC	2,000	-
28	150	160	15	2	< 1	1	1	1
29	154	168	1	< 1	< 1	< 1	< 1	1
30	138	182	10	4	-	2	3	-
31	148	187	0	1	0	15	0	0
32	154	190	< 1	0	0	0	0	0
33	140	190	0	0	1	0	3	0
34	140	190	1	0	0	0	1	1
35	154	160	1	1	1	0	0	5
36	148	180	2	1	0	0	0	0
37	144	185	0	1	0	0	0	0
38	162	150	0	0	0	0	0	0

Exhibit C

ECONOMICS LABORATORY, INC.
OSBORN BUILDING, ST. PAUL, MINNESOTA 55102

RESEARCH AND DEVELOPMENT DEPARTMENT TELEPHONE: (612) 451-5600

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MAR 28 1979
Executive Officer
Minn. Dept. of Health

File: 1810
Date: 9-14-78

Series: 6C
Report: 160

CONFIDENTIAL
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Continuation Of File Report 1746, Sanitizing Efficiency Of Low Temperature Warewashing Systems

By

Linda G. Crowell

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SANITIZING EFFICACY EVALUATION OF THE CHAMPION FW-60 LOW TEMPERATURE DISHMACHINE

ABSTRACT

Laboratory and field evaluations were performed on the Champion FW-60 Low Temperature Dishmachine to determine the sanitizing capabilities of these machines under challenging and realistic conditions. Results of controlled laboratory testing and field evaluation of processed dishware demonstrate that sanitization of contaminated dishware is achieved by the Champion FW-60 utilizing 50 ppm available chlorine in the final rinse.

The following is a summary of the laboratory and field evaluations performed on the Champion FW-60 dishmachine.

I. LABORATORY EVALUATION:

Testing procedures under any given set of conditions involved the application of a suspension culture of Staphylococcus aureus (10^8 cell/utensil) to the utensil (plates), or in the case of liquid food soils, to the food itself. A determination of the number of surviving organisms per utensil after processing was made according to the standard swab-rinse technique. Samples of wash water and rinse water were also taken to establish the presence of microorganisms in the system.

Inoculation of the utensils was as follows:

Test Conditions:

Water temperature in all tests was 140°F. Food soil included beef stew, animal fat (melted), potatoes, macaroni and cheese, fresh whole milk, and tomato juice. All plates (soiled foods) were dry prescraped representing a heavy soil load in the system.

A standard detergent concentration (.1%) was used. Sanitizing agent was NaOCl at 50 ppm available chlorine.

All runs were performed in Saint Paul City water using dishmachine's standard operating procedure.

Contamination Procedure:

Solid Food Soil - .5 mL of a broth culture of Staphylococcus aureus containing 10^8 cells per milliliter was pipetted onto each plate and uniformly spread over approximately 18 square inches and allowed to air dry one hour at room temperature. Food soil cooled to 45°C. was then applied and allowed to set one hour. Dishes were then prescraped and processed.

Liquid Soils - liquid soils were inoculated with the culture suspension so as to contain 10^6 cells per milliliter. Each glass was filled with the respective inoculated soil and emptied. Glasses were air dried one hour before processing. Uninoculated glasses were included in each test run to determine the deposition of bacteria back onto a surface.

Bacterial Recovery Procedure:

Immediately following dishmachine processing, the racks were removed and swab samples were taken of each inoculated utensil. The inoculated/soiled area of each plate and the rim and two-thirds of the inner surface of each glass were swabbed. Swab-vials containing the appropriate neutralizer buffer (sodium thiosulfate) were plated on Tryptocase Glucose Extract Agar. All plates were incubated at 37°C. for 48 hours. Bacteria counts are reported as total number of organisms per utensil.

Results:

As indicated by the data reported in Table I the Champion FW-60 under standard operating procedures and utilizing 50 ppm available chlorine in the final rinse reduced the number of inoculated bacteria to a level of less than 1 per utensil, except in those instances where gross food particles were not removed in the wash process.

It is interesting to note that the results of experiment #2 indicate that even when chlorine is not present in the final rinse that the physical action of the dishmachine and the use of detergent are capable of reducing significant numbers of bacteria.

II. FIELD EVALUATION

Microbiological field evaluation to measure the sanitizing efficacy of the Champion FW-60 Low Temperature Dishmachine under actual use conditions was performed at two local restaurants in

the Minneapolis area -- Ember's Restaurant (Hennepin & 26th) and Dudley Riggs (Seven Corners location). The study was conducted over a 6-month period (February, 1978 - August, 1978) and was performed in conjunction with Institutional's Warewashing Cost Comparison Study.

Comparative microbiological data was also obtained on a conventional, high temperature dishmachine (Hobart AM-9) which was in use at the Ember's Restaurant prior to the installation of the Champion FW-60.

The study involved a total of fifteen (15) visits to the Ember's Restaurant representing nine separate samplings of dishware processed by the Hobart AM-9 and six separate samplings of the Champion FW-60. Dudley Riggs was visited on three separate occasions and sampling was performed only on the Champion FW-60.

In order to determine the sanitizing efficacy, plate counts were performed on swab samples taken on randomly selected utensils immediately after processing.

The Food Service Sanitation Ordinance and Code recommended by the U.S. Public Health Service stipulates that effective bactericidal treatment is demonstrated by an average plate count per utensil examined of not more than 100 colonies.

Results:

Based on the above requirement the results of our study clearly demonstrate dishware processed by the Champion FW-60 under actual field conditions are well within the Public Health Standard of less than 100 colonies per utensil (Tables III and IV).

It is also interesting to note that even though the majority of swab counts (when averaged) from dishware processed by the high temperature dishmachine are within the public health standard the surviving number of organisms is consistently higher than those recovered from dishware processed by the Champion FW-60. (Table II)

III. CONCLUSIONS

The microbiological evaluation of the Champion FW-60 Low Temperature Dishmachine both under controlled conditions in the laboratory, and under actual use conditions in the field demon-

strate that sanitization of contaminated eating utensils is achieved by the presence of 50 ppm available chlorine in the final rinse.

Laboratory data showed a significant reduction in the numbers of bacteria on highly contaminated dishware except in those situations where gross soil particles were not removed during the washing process.

Microbiological field evaluations on utensils processed by the Champion FW-60 dishmachine under standard operational procedures demonstrate that public health standards of cleanliness and sanitation are consistently met.

TABLE I

LABORATORY EVALUATION OF THE CHAMPION FW-60

OPERATIONAL CONDITIONS		WASH H_2O BACTERIAL COUNT	SOILS	NO. OF PLATES SAMPLES	AVG. COUNT OF SURVIVING ORGANISMS
EXPERIMENT #1		6×10^3/mL			
			Beef Stew	5	<1
Detergent:	.1%		Animal fat	5	<1
Chlorine:	50 ppm		Macaroni	5	TNTC*
Rinse additive;	200 ppm		Milk	5	<1
			Tomato juice	5	<1
			uninoculated glass	5	<1
EXPERIMENT #2		2.4×10^4/mL			
Detergent:	.1%		Beef stew	5	121
Chlorine:	not used		Animal fat	5	2
Rinse additive:	200 ppm		Macaroni	5	TNTC*
			Milk	5	55
			Tomato juice	5	15
			uninoculated glass	5	30
EXPERIMENT #3		3×10^4/mL			
Detergent:	not used		Beef stew	5	1200
Chlorine:	not used		Animal fat	5	52
Rinse additive:	not used		Macaroni	5	TNTC*
			Milk	5	TNTC
			Tomato juice	5	TNTC
			uninoculated glass	5	50

NOTE * = food soil remaining on utensil
TNTC = Too Numerous To Count

TABLE II

MICROBIOLOGICAL FIELD EVALUATIONS

CONVENTIONAL HIGH TEMPERATURE DISHMACHINE (HOBART AM-9)
(EMBERS RESTAURANT)

DATE OF SAMPLING	OPERATIONAL CONDITIONS	UTENSILS SAMPLED	NUMBER SAMPLED	SURVIVING ORGANISMS RANGE	SURVIVING ORGANISMS AVG. COUNT PER UTENSIL
2-9-78	Wash temp: 150°F. Rinse: 162°F.	Plates	6	0 - 3	1
		Saucers	4	0 - 102	25
		Glasses	4	7 - 43	17
		Forks	3	0	0
		Spoon	1	37	37
		Vegetable Container	1		225
2-16-78	Wash temp: 167°F. Rinse: 170°F.	Plates	3	0 - 1	1
		Bowl	1	0	0
		Spoon	1	4	4
2-23-78	Wash temp: 165°F. Rinse: 170°F.	Plates	3	1 - 4	2
		Saucers	3	1 - 3	2
		Cups	4	0 - 180	29
		Glasses	3	0 - 25	7
		Creamer	2	2 - 4	3
3-2-78	Wash temp: 167°F. Rinse: 172°F.	Glasses	3	0 - 8	4
		Plates	5	0 - 6	3
		Saucers	5	0 - 220	62
		Cups	5	0 - 2	1
3-10-78	Wash temp: 165°F. Rinse: 170°F.	Plates	2		
		Saucers	2		
		Spoons	3	0 - 9	2
		Forks	2	0 - 1	1
		Knife	1	39	39
		Bowl	2	25 - 34	30
		Vegetable Container	1	46 - 168	62
3-17-78	Wash temp: 165°F. Rinse: 170°F.	Glasses	6	8 - 500	108
		Knives	3	0 - 8	4
		Forks	4	0 - 7	2
		Spoons	4	0 - 20	6

TABLE II (CONTINUED)

DATE OF SAMPLING	OPERATIONAL CONDITIONS	UTENSILS SAMPLED	NUMBER SAMPLED	SURVIVING ORGANISMS RANGE	SURVIVING ORGANISMS AVG. COUNT PER UTENSIL
3-23-78	Wash temp: 162°F. Rinse: 172°F.	Plates	5	10 - 20	14
		Glasses	5	51 - 108	82
		Cups	5	1 - 8	5
		Spoons	5	6 - 28	16
		Forks	5	3 - 9	8
3-30-78	Wash temp: 166°F. Rinse: 176°F.	Plates	5	0 - 3	1
		Glasses	1	1	1
		Cups	4	3 - 10	3
		Saucers	5	0	0
		Forks	4	0 - 190	65
		Spoons	4	0 - 6	2
4-7-78	Wash temp: 178°F. Rinse: 180°F.	Glasses	5	24 - 50	
		Forks	3	0 - 6	3
		Knives	3	0	0
		Spoons	4	0 - 9	3
		Plates	5	0 - 2	1
		Saucers	2	0 - 11	3

TABLE III

MICROBIOLOGICAL FIELD EVALUATIONS

CHAMPION FW-60 LOW TEMPERATURE DISHMACHINE
(EMBERS RESTAURANT)

DATE OF SAMPLING	OPERATIONAL CONDITIONS	UTENSILS SAMPLED	NUMBER SAMPLED	SURVIVING ORGANISMS	
				RANGE	AVG. COUNT PER UTENSIL
4-19-78	Wash temp: 156°F. Rinse: 142°F. Cl_2 conc: 58 ppm	Plates	15	0	0
		Glasses	6	0 - 56	13
		Forks	5	0 - 16	2
		Spoons	5	0 - 35	7
		Cups		0	0
6-27-78	Wash temp: 118°F. Rinse: 118°F. Cl_2 conc: 68 ppm	Cups	3	0 - 4	1
		Glasses	9	0 - 1	1
		Spoons	3	0	0
		Forks	4	0	0
		Plates	8	0	0
7-6-78	Wash temp: 122°F. Rinse: 122°F. Cl_2 conc: 39 ppm-- 44 ppm	Glasses	5	0 - 32	6
		Cups	5	0	0
		Forks	6	0	0
		Spoons	5	0	0
		Plates	4	0 - 4	1
7-13-78	Wash temp: 120°F. Rinse: 120°F. Cl_2 conc: 62 ppm	Cups	6	0 - 4	1
		Glasses	6	0	0
		Spoons	6	0	0
		Forks	5	0	0
		Plates	5	0	0
7-27-78	Wash temp: 118°F. Rinse: 118°F. Cl_2 conc.: N.R. (test kit damaged)	Glasses	5	2 - 5	4
		Plates	5	0 - 1	4
		Forks	5	1 - 8	4
		Spoons	5	0 - 12	3
8-10-78	Wash temp: 122°F. Rinse: 122°F. Cl_2 Conc: N.R.	Glasses	10	0 - 35	4
		Cups	6	0	0
		Spoons	5	0 - 6	1
		Forks	10	0 - 1	<1

NOTE: N.R. = Not Recorded

TABLE IV

MICROBIOLOGICAL FIELD EVALUATIONS

CHAMPION FW-60 LOW TEMPERATURE DISHMACHINE
(DUDLEY RIGGS)

DATE OF SAMPLING	OPERATIONAL CONDITIONS	UTENSILS SAMPLED	NUMBER SAMPLED	SURVIVING ORGANISMS RANGE	SURVIVING ORGANISMS AVG. COUNT PER UTENSIL
6-27-78	Wash temp: 125°F.	Glasses	4	0	0
	Rinse: 125°F.	Cups	5	0	0
	Cl_2 conc: 75 ppm	Glasses	4	0	0
		Plates	4	0	0
		Forks	5	0 - 3	1
		Spoons	4	0	0
7-13-78	Wash temp: 132°F.	Cups	7	0	
	Rinse: 132°F.	Glasses	7	0	
	Cl_2 conc: 44 ppm	Forks	7	0	
		Spoons	5	0	
7-27-78	Wash temp: 115°F.	Glasses	10	0 - 2	<1
	Rinse: 122°F.	Cups	1	0 - 2	<1
	Cl_2 conc: N.R.				

NOTE: N.R. = Not Recorded

EXHIBIT D

RECEIVED
MAR 28 1979
Executive Officer
Minn. Dept. of Health

SANITIZING EFFICACY OF LOW TEMPERATURE WAREWASHING SYSTEMS SUMMARY OF LABORATORY & FIELD EVALUATIONS (1977-1978)

Presented at the Annual Meeting of the Directors of the Massachusetts Public Health Association -- October, 1978.

With the increased cost and reduced availability of energy the warewashing industry is looking to alternate methods of cleaning and sanitizing dishware.

As a result manufacturers of warewashing systems have responded to the needs of the industry and the energy problem by marketing new commercial chemical sanitizing dishmachines frequently referred to as low temperature dishwashers. These chemical sanitizing dishmachines are identical to their counterpart the conventional high temperature dishmachine except they utilize a chemical sanitizer, sodium hypochlorite, in the final rinse water in lieu of the 180°F final rinse temperature for sanitizing dishware.

Chemical Sanitizing dishmachines are not new. In fact they have been provided for in various regulations. What is new, however, is their growing popularity and their widespread acceptance throughout the industry. As a result questions are being raised as to their ability to clean and sanitize effectively.

Extensive information exists on the sanitizing and cleaning performance of conventional high temperature dishmachines with a final rinse of 180°F, but unfortunately very little data, if any, is available to document the capabilities of these low temperature dishmachines.

As a result, Economics Laboratory, as supplier of chemical detergent and sanitizers, initiated laboratory and field evaluation studies to determine the compliance of these dishmachines with public health standards of cleanliness and sanitation.

It is generally accepted that adequate removal of food soil is a prerequisite to any sanitizing process, therefore cleaning efficiency tests were performed to evaluate the various operational conditions which affect cleaning cleaning results and to establish the limits within which achievable results could be obtained.

Results of these studies indicated, as you will see, that temperature and soil concentration are the most significant factors affecting cleaning and subsequent sanitization. Based on these results microbiological tests were designed with these parameters in mind to evaluate the sanitizing ability of these dishmachines under realistic and challenging conditions.

Laboratory test procedures under any given set of conditions involved the application of a broth culture of Staphylococcus aureus to the respective utensils. Due to the tremendous dilution factor of the wash water preliminary tests indicated that an inoculation of 10^8 (100,000,000 bacteria) cells were needed on each utensil in order to consistently recover 10^4 (10,000) cells/ml in the wash water.

Nine representative food soils including both solid and liquid soils were applied to the respective utensil and allowed to dry one (1) hour prior to prescraping and processing. Solid foods included beef stew, animal fat, macaroni/cheese, and instant mashed potatoes. Liquid included cocoa, whole milk, tomato juice, orange juice and tea.

Prescraping, an important factor influencing cleaning, was handled in two ways.

1.) A poor prescraping procedure involving a dry scraping of the dishware to remove primarily the gross food soils. This would be considered a heavy soil load to the system.

2.) A good prescraping procedure or wet prescraping which involved the flushing of the utensil with water to remove not only the gross food soils but also wets the remaining soil and facilitates its removal during the washing process.

Processing of the utensils was then performed under various water temperatures. A standard detergent concentration (0.1%) and the minimum concentration of sodium hypochlorite (50 ppm available Cl_2) was used in all cases, except where no products were used and dishware was washed with only water.

Immediately following processing racks were removed and swab samples were taken of each inoculated utensil. Recovery of the bacteria from the swabs was performed according to standard microbiological procedures.

RESULTS:

SLIDE I: This slide represents the number of bacteria surviving on contaminated dishware processed at 120°F with (gold column) and without (blue column) the use of any product and under both good and poor prescraping conditions.

The United States Public Health Service has set a standard for effective sanitization of not more than 100 organisms per utensil sampled.

The results of this test clearly demonstrate:

1) The effect prescraping has on cleaning and subsequently sanitization, remember cleaning is a function of sanitization.

2) Most important is that with the proper use and dispensing of detergent and chemical sanitizer (50 ppm sodium hypochlorite) that sanitization of contaminated utensils is achieved even under poor or heavy soil conditions.

NOTE: 100,000,000 bacteria per utensil were reduced to less than 100.

SLIDE II: This slide represents the number of surviving bacteria on dishware processed at 140°F under the same test conditions.

Results demonstrate

1) the significant effect temperature has on the removal of soils.

2) the cumulative effect good prescraping and increased temperatures have on improved cleaning results

3) with proper utilization of detergent and chemical sanitizer that sanitization of dishware is achieved.

In conjunction with laboratory studies, field evaluation studies were also performed under actual commercial use conditions.

SLIDE III: This slide represents the results of a recent study conducted at a typical food service establishment that utilized both a conventional high temperature dishmachine (Hobart AM9) and a low temperature recirculated wash type.

During the months of February, March, and April microbiological swab samples were taken on randomly selected dishware, processed by a conven-

tional high temperature dishmachine. Final Rinse temperatures were also noted. Results are plotted on the graph.

Results indicate that even though the bacterial count from the processed dishware is within public health standards, bacteria are still surviving. In addition, rinse temperatures fluctuated during this time from 161°F - 180°F and the bacterial counts correlate with the temperature, i.e.: when the temperature decreases the bacteria counts increase and vice versa.

Then in mid-April the conventional high temperature dishmachine was replaced with a low temperature dishmachine and again microbiological monitoring was performed on processed dishware over a 4½ month period. Wash temperatures and chlorine concentration levels were also recorded during this period.

As you can see, the water temperatures were low and in most cases less then the 120°F as required by NSF, however the residual chlorine level remained constant and above the minimum concentration level of 50 ppm available chlorine throughout the test period. In all instances the number of surviving organisms on processed dishware was consistently low and definitely well within the public health requirement of less than 100 colonies per utensil.

To summarize, in all laboratory tests conducted, proper sanitization of highly contaminated eating utensils was achieved by the presence of 50 ppm available chlorine within the final rinse.

The field studies indicate that the low temperature warewashing system can meet the public health requirements for a sanitized eating utensil, and is comparable to the real world situation with the conventional high temperature warewashing.

There is one other significant point that I would like to make and that is the use of an EPA registered sanitizer. All products making a sanitizing or disinfectant claim must be registered with the Environmental Protection Agency (EPA) and data documenting the safety and efficacy of the product must be submitted. In addition the labeling must show adequate use directions and a means of determining that the proper use concentration is used.

LABORATORY EVALUATION

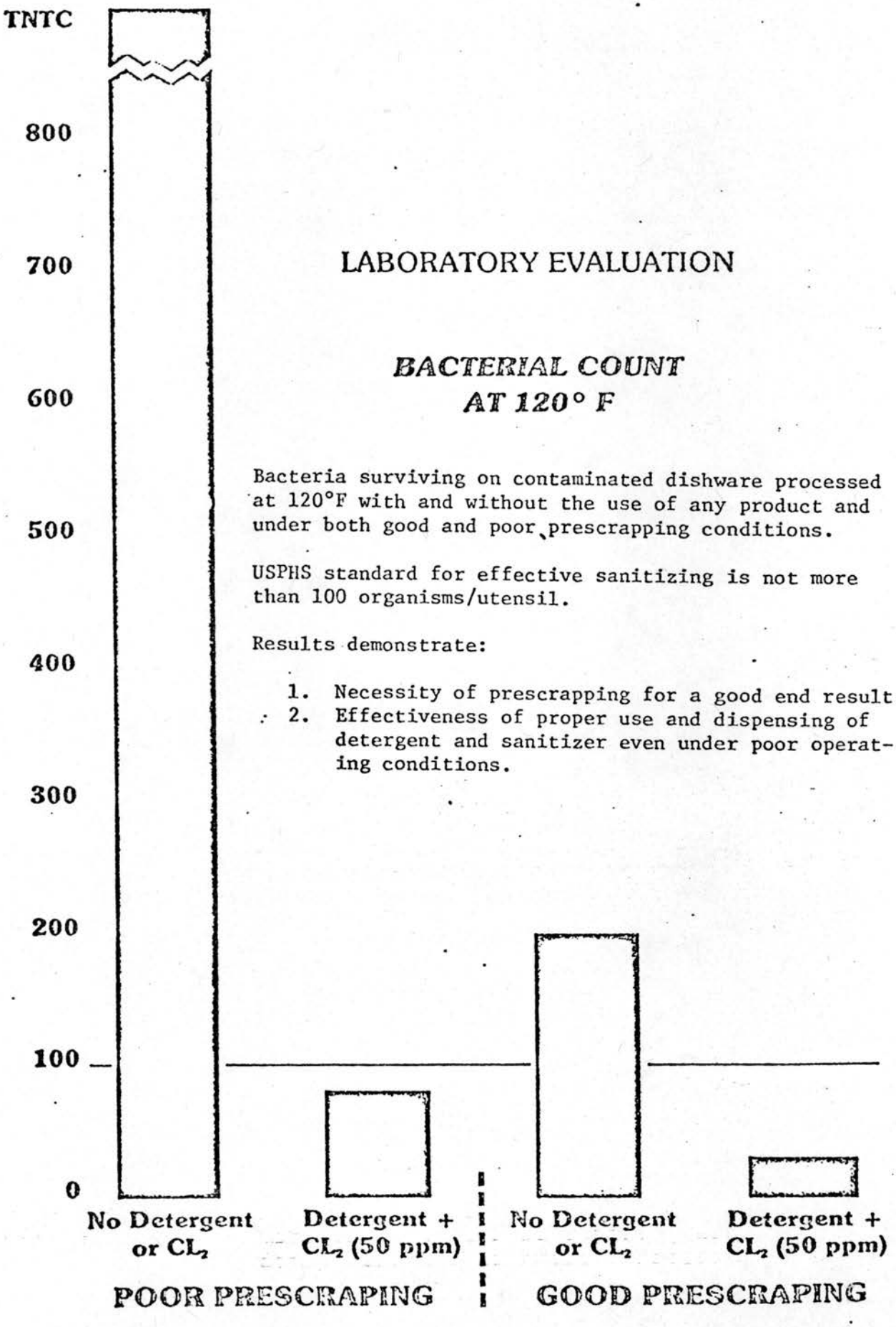
BACTERIAL COUNT AT 120° F

Bacteria surviving on contaminated dishware processed at 120°F with and without the use of any product and under both good and poor prescrapping conditions.

USPHS standard for effective sanitizing is not more than 100 organisms/utensil.

Results demonstrate:

1. Necessity of prescrapping for a good end result.
2. Effectiveness of proper use and dispensing of detergent and sanitizer even under poor operating conditions.



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TNTC

800

700

LABORATORY EVALUATION

600

BACTERIAL COUNT AT 140° F

500

Bacteria surviving on contaminated dishware processed at 140°F with and without the use of any product and under both good and poor prescrapping conditions.

Results demonstrate:

1. Significant effect of temperature on soil removal
2. Positive cumulative effect of increased temperature and good prescrapping on cleaning results.
3. Superior sanitizing result achieved with proper use of detergent and chemical sanitizer.

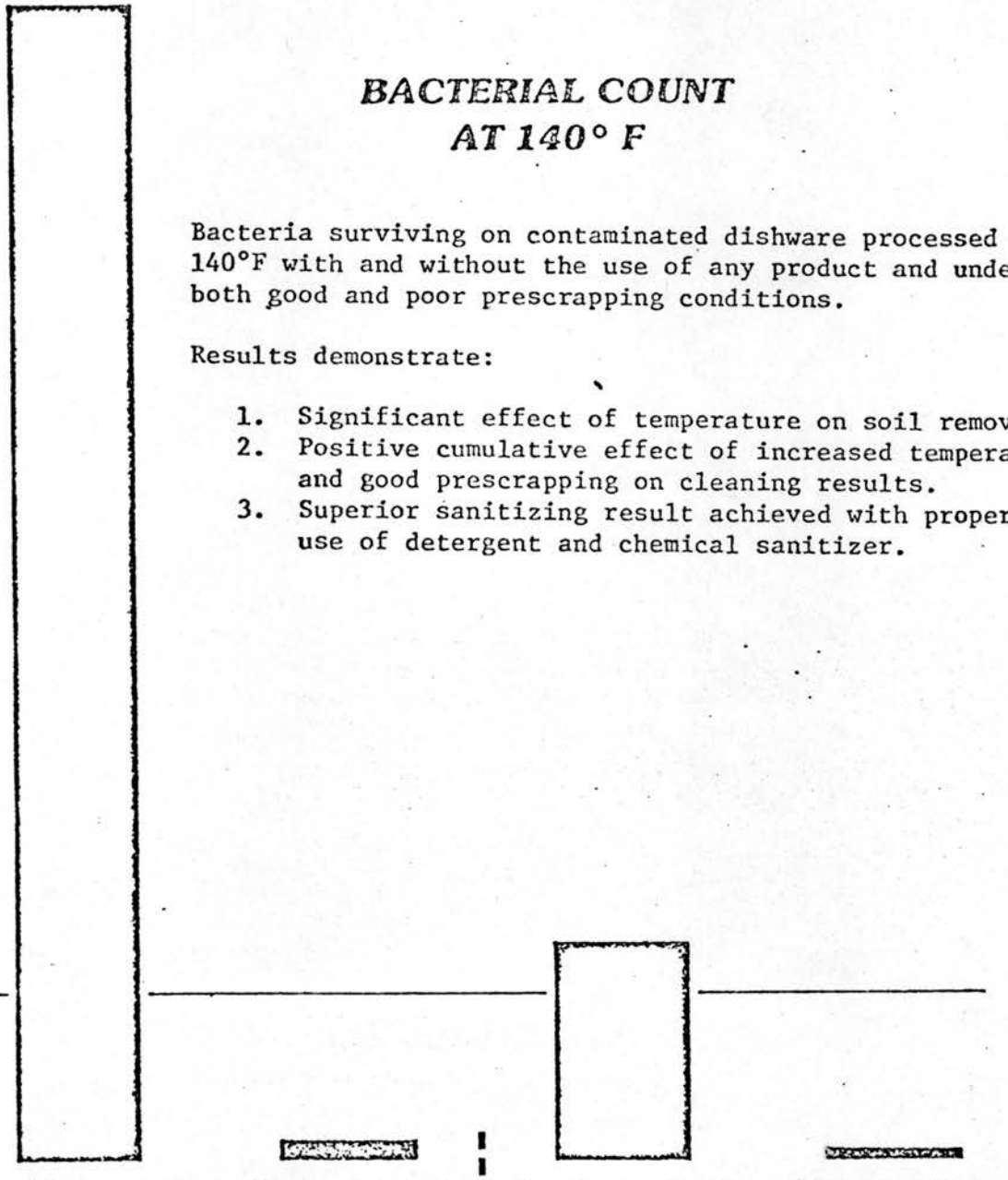
400

300

200

100

0



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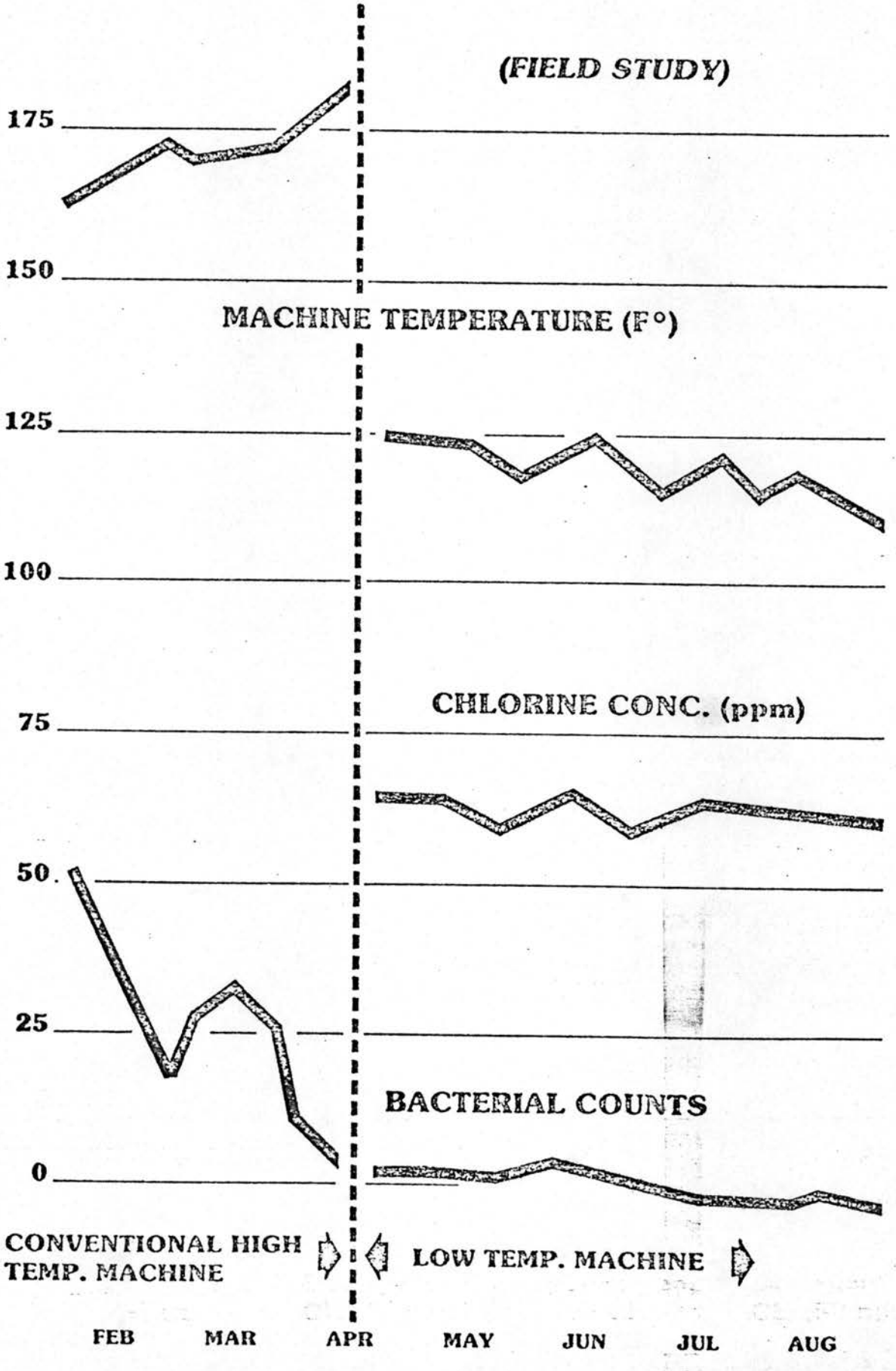

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6 Month Field Study

High Temperature vs. Low Temperature Dishmachine

Typical food service establishment used the conventional high temperature dishmachine for 2½ months and then changed over to the low temperature - chemical sanitizing operation.

Results demonstrate:

1. In the conventional machine rinse temperatures fluctuated between 161°F and 180°F and bacterial survival increases as rinse temperatures drop.

2. Water temperatures frequently dropped below the 120°F required, but the chlorine concentrations remained constantly above the required minimum and bacterial counts remained low.

HLTH-80-040-GB

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes.

REPORT OF THE HEARING EXAMINER

The above-entitled matter came on for hearing before State Hearing Examiner George A. Beck at 9:30 a.m. on Tuesday, April 1, 1980, in Room 105 of the Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota. The hearing was concluded on April 2, 1980.

This Report is a part of a rule hearing procedure pursuant to Minn. Stat. §§ 15.0411 to 15.0417 and 15.052 to determine whether the proposed rules and rule amendments should be adopted by the Department of Health. A copy of this Report may be obtained from the Office of Hearing Examiners for the cost of reproduction.

Members of the agency panel appearing at the hearing included: Mike Tripple, Assistant Section Chief, Survey and Compliance Section, Minnesota Department of Health; Nancy Younger, Management Analyst, Survey and Compliance Section, Minnesota Department of Health; and John A. Breviu, Special Assistant Attorney General, representing the Minnesota Department of Health.

Sixty-nine persons signed the hearing register. Fifteen public witnesses appeared and spoke at the hearing. The Department submitted 17 written exhibits. Thirty-three timely written comments were received from the public prior to the close of the record.

Pursuant to Minn. Stat. § 15.0412, subd. 4 (1978), this Report shall be available for review to all affected individuals upon request for at least five days. Thereafter, the Department of Health shall, if it proposes to adopt the rules as originally proposed or amended, submit a copy of the Order Adopting Rules, a copy of any additional agency findings, a copy of the rules as originally proposed, and a copy of the rules as adopted to the Chief Hearing Examiner for review pursuant to Minn. Stat. § 15.052, subd. 4 (1978). The submission to the Chief Hearing Examiner shall precede review by the Attorney General. The Chief Hearing Examiner shall complete his review and submit his report to the Department on the issues of substantial changes in the rule and compliance with Minn. Stat. § 15.0412 (1978) within ten calendar days. The Department will be responsible for filing the rules with the Attorney General and for notifying persons who have indicated that they wish to be notified of such filing.

Based upon all the testimony, exhibits and written comments, the Hearing Examiner makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On February 26, 1980, the Department of Health filed the following documents with the Chief Hearing Examiner:

(a) A copy of the proposed rule amendments.
(b) The Order for Hearing.
(c) The Notice of Hearing proposed to be issued.
(d) A statement of number of persons expected to attend and length of hearing.

2. On February 25, 1980, the Notice of Hearing and the amendments as proposed were published at 4 State Register 317.

3. On February 26, 1980, the Notice of Hearing was mailed by the Department to all persons and associations who had registered their names with the Secretary of State to receive such notice, as well as to a supplementary list of nursing homes and boarding care homes and to a list of persons and associations known by the Department to be interested in departmental regulation and to all the members of the Minnesota Legislature.

4. On March 6, 1980, the Department filed the following documents with the Hearing Examiner:

(a) The Affidavit of Receipt of the Secretary of State's list.
(b) The Certificate of the Secretary of State.
(c) The Affidavit of Mailing of the Notice of Hearing.
(d) A Notice of Intent to obtain information published in the State Register on November 8, 1976, and materials received following the Notice.
(e) A Petition from Non-Agency Source requesting a rules hearing.
(f) The Statement of Need and Reasonableness.

The documents listed above were available for inspection at the Office of Hearing Examiners from the date of filing to the date of the hearing.

5. The record remained open through April 21, 1980, for the receipt of written comments and statements.

Statutory Authority

6. The Department of Health has cited three statutes as authority for the promulgation of the rule amendments; namely, Minn. Stat. §§ 144.56, 144A.08 and 144A.10 (1978). Minn. Stat. § 144.56 reads, in part, as follows:

> 144.56 STANDARDS. Subdivision 1. The state commissioner of health shall, in the manner prescribed by law, adopt and enforce reasonable rules, regulations, and standards under sections 144.50 to 144.56 which he finds to be necessary and in the public interests and may rescind or modify them from time to time as may be in the public interest, insofar as such action is not in conflict with any provision thereof.
>
> Subd. 2. In the public interest the commissioner of health, by such rules, regulations, and standards, may regulate and establish minimum standards as to the construction, equipment, maintenance, and operation of the institutions insofar as they relate to sanitation and safety of the buildings and to the health, treatment, comfort, safety, and well-being of the persons accommodated for care. Construction as used in this subdivision means the erection of new buildings or the alterations of or additions to existing buildings commenced after the passage of this act.

Minn. Stat. § 144A.08, subd. 1 provides as follows:

144A.08 PHYSICAL STANDARDS; PENALTY. Subdivision 1. Establishment. The commissioner of health by rule shall establish minimum standards for the construction, maintenance, equipping and operation of nursing homes. The rules shall to the extent possible assure the health, treatment, comfort, safety and well being of nursing home residents.

Minn. Stat. § 144A.10, subd. 4 provides as follows:

Subd. 4. Correction orders. Whenever a duly authorized representative of the commissioner of health finds upon inspection of a nursing home, that the facility or a controlling person or an employee of the facility is not in compliance with sections 144A.01 to 144A.17 or the rules promulgated thereunder, a correction order shall be issued to the facility. The correction order shall state the deficiency, cite the specific rule or statute violated, state the suggested method of correction, and specify the time allowed for correction. The commissioner of health by rule shall establish a schedule of allowable time periods for correction of nursing home deficiencies.

Minn. Stat. § 144A.10, subd. 6 provides as follows:

Subd. 6. Fines. 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 promulgated by rule of the commissioner of health. 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 $250 per day of noncompliance.

LCRAR

7. Most of the rule amendments proposed in the rule proceeding are based upon recommendations made by the Legislative Commission to Review Administrative Rules. (Ex. 10, Attachment A) On January 29, 1980, the LCRAR voted to request the Department of Health to hold a public hearing within 60 days of receipt of the request by the Department. The request was received by the Department of Health on February 5, 1980.

Compliance with § 15.0412, subd. 7

8. Minn. Stat. § 15.0412, subd. 7 provides as follows:

Subd. 7. If the adoption of a rule by an agency will require the expenditure of public moneys by local public bodies, the notice of the proposed rule as required by this section shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies in the state to implement the rule for the two years immediately following adoption of the rule if the estimated total cost exceeds $100,000 in either of the two years. For purposes of this section, local public bodies shall mean officers and governing bodies of the political subdivisions of the state and other officers and bodies of less than state wide jurisdiction which have the authority to levy taxes.

The Department did not include a written estimate with its Notice of Hearing as called for in this section. Both the Minnesota Association of Health Care Facilities (MAHCF) (Ex. FF, p. 3) and the law firm of Broeker, Hartfeldt, Hedges & Grant ("the Broeker firm") (Ex. GG, p. 3) believe that the costs of implementing the proposed amendments will exceed the statutory threshold. The MAHCF stated that since Minnesota counties pay approximately 4.43% of all

medical assistance costs, should these proposed rule amendments cause a statewide increase in expenditures of $2,256,336, then the $100,000 threshold in the statute would be exceeded. (This estimate does not appear to consider that only two-thirds of nursing home costs statewide are paid by medical assistance.) Additional costs created by the proposed amendments were cited as chest x-rays for residents upon admission and costs of tuberculosis testing for employees.

9. The Department replied that prior to issuing the Notice of Hearing, it had reviewed the subject matter of the proposed rules and determined that they would not require any expenditures by local bodies in excess of $100,000. (Ex. 17, p. 17) The Department estimates that the cost of tuberculosis screening for employees required by the rule amendments will cost somewhere between approximately $12,000 to $26,000 for the 90 publicly run facilities in the state. Presumably a similar cost would exist for the 360 some private homes reduced to the 4.43% figure for purposes of estimating the cost to local public bodies. Assuming that approximately two-thirds of the patients in nursing homes in Minnesota are medical assistance recipients, and assuming that counties contribute less than 5% of medical assistance costs, it would appear that the maximum cost increase for x-rays that the counties would have to bear would be in the neighborhood of $5,000. The Department believes that, as is explained further in its Statement of Anticipated Costs and Benefits, the remaining rules provide options to facilities and, thus, do not require expenditures by local public bodies until that option is exercised. (Ex. 17, p. 17) The record would not appear to support the contention that the proposed rule amendments would cause total costs in excess of $100,000 per year for local public bodies.

Statement of Anticipated Costs and Benefits

10. Minn. Stat. § 144A.29, subd. 4 states as follows:

> Each rule promulgated by the commissioner of health pursuant to section 144A.01 to 144A.17 shall contain a short statement of the anticipated costs and benefits to be derived from the provisions of the rule.

The Department did prepare a seven-page document pursuant to this statute. The Department estimated increased cost for only one rule; namely, the amendment to Section 1.047 A. in regard to tuberculosis testing of employees. In regard to several of the rules, the Department stated that it was not in the position to provide an indication of anticipated costs since the rules provided an option to the facility, such as the rules relating to handling of funds and the amendment proposed governing the administration of oxygen.

11. The MAHCF stated that the rules in regard to variances, the schedule of fines, and the allowable periods for correction will have costs to nursing homes and suggested that merely because it would be difficult for the Department to estimate costs, it does not mean that the Department need not make any attempt to do so. It also suggested that in fact since most facilities do handle patient funds, there will be increased costs as a result of the proposed rule amendment in that regard. (Ex. FF, pp. 2-3) The Broeker firm believes that the statement is deficient in that the Department has considered

only the costs which nursing homes will incur as a result of the rule amendments where it should have considered also the cost impact on the Department of Health itself, upon the resident, and upon the medical assistance program. (Ex. GG, p. 2; Tr. pp. 63-66) The Broeker firm also objected to the Department's failure to discuss the cost impact of the daily tagging system with its reinspection cost. The Broeker firm stated that the question of whether or not greater fines provide a greater deterrent should have been balanced in the statement, and that a discussion of the costs to the Department to enforce this new system should have been discussed. (Tr. pp. 222-230; Ex. GG, p. 29) The Broeker firm also criticized the Department's estimation in regard to the patient funds rule. They stated that in reality most nursing homes will handle patient funds and all will if the federal regulations as expected compel them to do so. Therefore, the Department should have attempted to estimate costs rather than simply stating that the rule was not mandatory. (Tr. pp. 99-100; Ex. GG, pp. 10-11) The Broeker firm also commented that no estimate of anticipated costs was made for the waiver rule or the requst for extension rule which they believe will show costs for staff time of the Department, as well as the provider. (Ex. GG, p. 24, 32; Tr. pp. 178-180)

12. The Department replied that it can reasonably be inferred that since the statute uses the phrase "short statement" an elaborate analysis is not required. The Department stated that the statute only requires an analysis of the costs the nursing homes will incur since the costs associated with the Department's enforcement is subject to detailed legislative scrutiny through the budget process. The Department reiterated that where the rules are not mandatory, it is not possible to anticipate costs since the number of facilities exercising the option is not known and cannot be estimated. (Ex. 17, p. 18)

13. The Department is correct in pointing out that the legislature did not intend a detailed statement of anticipated costs. It is clear, however, that it was intended that the Department should weigh costs against benefits in the process of rule promulgation. This goal is frustrated when the Department's effort stops at simply stating that a rule is not mandatory and, therefore, costs cannot be estimated. The spirit of the statute should require the Department to estimate what costs it believes will actually result. This would include an estimate as to how many facilities will comply or take advantage of the proposed rule. The record in this matter suggests that whether or not the federal regulations are promulgated, a large number of facilities would choose to handle patient funds under this proposed rule, and the Department could have made an estimate of the cost to the nursing home. The Department's interpretation of the statute as speaking only to costs to be incurred by facilities is reasonable. The Department has, nonetheless, met the minimum requirements of Section 144A.29, subd. 4, which does not impose a very heavy burden upon the Department.

Fiscal Note

14. The Department is also required by Minn. Stat. § 15.065 (1979 Supp.)

to file with the House Appropriations and the Senate Finance Committees a fiscal note if any rule has a fiscal impact in excess of $100,000 per year. (Ex. GG, p. 5; Ex. FF, p. 4) The statute requires that this be done before the rule is "put into effect". This statute is not limited to the effect upon local public bodies. The Department has stated that it will reevaluate the cost of the proposed rules and file the fiscal note, if required. (Ex. 17, p. 18)

Statement of Need and Reasonableness

15. Both the MAHCF and the Broeker firm made general criticisms of the Statement of Need and Reasonableness. The MAHCF stated that the Statement lacked specificity and did not contain facts but only general conclusions. (Ex. FF, pp. 1-2) The Broeker firm stated that the Statement was inadequate because it generally concludes that reasonableness is present without looking at the specific facts, alternatives or other relevant considerations. (Ex. GG, pp. 1-2) Although the adequacy of the Statement in regard to particular rules will be discussed later in this Report, it can be noted that a rule may, where apropriate, be supported by argument and reasoning as well as facts. Chapter 15 does not specifically require an agency to discuss possible alternatives, but only to support its own proposal.

Proposed Amendment to 7 MCAR § 1.048 A.8. - Record of Patients' and Residents' Funds

16. This proposed amendment sets up a specific procedure for the handling of resident funds by nursing and boarding care homes. It was suggested before the LCRAR that funds had been handled without proper authorization, commingling of funds had occurred, and that there was a lack of safeguards. The Minnesota Board on Aging spoke in support of the proposed rule amendments, citing three major recent fraud investigations regarding patient funds in Minnesota. The Board believes that a standard set of procedures will help to cure the problem. (Ex. M, pp. 1-3)

17. Both the MAHCF (Tr. p. 85; Ex. FF, p. 4) and the Broeker firm (Tr. p. 98; Ex. GG, p. 10) urged that this proposed rule amendment be withdrawn at this time and promulgated after the promulgation of a similar federal regulation so that consistency can be obtained. According to the record, there would be at least one difference, with the federal regulations having a different, although not necessarily inconsistent, requirement in regard to placing funds with financial institutions. The Department stated that it hoped to achieve consistency with future federal regulation, but believed that it should proceed with the proposed rule amendment at this time since it has the responsibility to provide for the well being of nursing home residents. The Department stated that it will review the federal regulation when it is finalized and should some inconsistency appear, propose an amendment to the state rule in question at a rulemaking hearing later this year. (Ex. 17, p. 3) The Broeker firm suggested, as it has in regard to a number of rules, that this rule is more than a "minimum standard", which they suggest is called for by the statute enabling the rules. (Tr. p. 98) The sense of the statute,

however, would seem to be that the Department is directed to set certain threshold standards which nursing and boarding care homes must meet, but not to preclude a detailed statement of what is required. The Broeker firm also raised the serious question of how an incompetent nursing home resident who is without relatives is to be treated under this rule without violating the proposed rule. They believe that this is a common situation which the rule does not address. (Ex. GG, p. 14)

18. The Minnesota Association of Homes for the Aging (MAHA) suggested, for the sake of consistency, that the term "legal guardian" be used wherever "guardian" appears in the rule in order to make the proposed amendment consistent. (Ex. J, p. 3) The Department agreed to this suggestion. (Ex. 17, p. 3)

19. Proposed amendment 1.048 A.8.a. requires the facilities' admission policies to specify whether or not the home will accept personal funds of residents for safekeeping. The Broeker firm suggested that the title of this subsection should be amended to read "Admission Policy". (Tr. p. 100; Ex. GG, p. 14) The Department agreed that this change should be made. (Ex. 17, pp. 3-4) The Board on Aging (Ex. M, p. 3), Friends and Relatives of Nursing Home Residents (FRNHR) (Ex. O, p. 1), the Nursing Home Residents Advocates (NHRA) (Tr. p. 82), and the Nursing Home Residents Advisory Council (NHRAC) (Ex. EE, p. 1), all stated that the proposed amendment should require nursing homes to handle patient funds when requested to do so rather than leaving the decision up to the facility. They stated that a bank or other financial institution is often inaccessible for a resident and that they are, therefore, effectively denied access to their funds if the nursing home declines to handle personal funds of residents. The MAHCF testified that the safekeeping of patient funds should be voluntary, and suggested that a mandatory rule would be beyond the statutory authority of the agency. (Tr. p. 86; Ex. FF, p. 4) In its written comments, the Department correctly states that an amendment of this rule subsection to make the handling of patient funds mandatory would be a substantial change which the Department would have to make in a subsequent rulemaking proceeding. The Department stated that they will consider the comments made for a possible later change in the rules. (Ex. 17, p. 4) The subsection is needed and reasonable as proposed.

20. Subsection 1.048 A.8.c.(3) prohibits the commingling of patient funds from one facility with those of another, even though the facilities might be owned by one corporation. The Department stated that this would provide a clear identity of funds from each nursing home for accounting purposes and provide for accessibility to these funds. The Board on Aging supported the proposed amendment, and stated that residents of one facility should not suffer if a related facility has financial difficulties. (Ex. AA, p. 1) The MAHA suggested deletion of this proposed amendment. (Ex. J, p. 3) The Broeker firm stated that the Department's presentation in support of this rule was inadequate since it was mostly conclusory and did not provide specific facts. (Ex. GG, pp. 11, 14) The Department stated that the subsection is intended to ensure that the personal funds of patients in one facility can be clearly identified from those funds of residents in another facility. (Ex.

17, p. 4) The amendment is needed and reasonable as proposed. Facts showing the reasonableness of a proposed rule need not necessarily be adjudicative, trial-type facts, but can also be legislative facts or argument in support of policy. St. Paul Area Chamber of Commerce v. Minnesota Public Service Commission, 251 N.W.2d 350, 356-7 (Minn. 1977); Davis, Administrative Law of the Seventies, Sec. 6.01-2 (Cumulative Supp. 1977, p. 65).

21. Section 1.048 A.8.c.(4)(a) provides for access to all written records in regard to personal funds and by implication, restricts access to the resident, the resident's legal representative or a person designated by the resident. The rule, as proposed, requires a minimum access of one hour five days per week. The Board on Aging (Ex. M, p. 4), FRNHR (Ex. O, p. 2), NHRA (Tr. p. 83), and the NHRAC (Ex. EE, p. 1), stated that access should be allowed at any time during the facility's normal business hours. The MAHCF stated that access should be left to each facility with no minimum stated since access could be disruptive to a facility's normal operations. (Tr. p. 87; Ex. FF, p. 5) The Department stated that it believes that the facility is in the best position to establish reasonable times for access and and concluded that it would propose deleting the last sentence of the subsection as originally proposed and substituting the following: "Such policy shall assure that access be provided in accordance with the needs of the patients and residents." The Department states that this language would require that the facility carefully consider the needs of residents and establish periods of access in accordance with those needs. (Ex. 17, p. 4) It is concluded that this subsection, as proposed to be amended by the Department, has been shown to be needed and reasonable. It is suggested, however, that the Department consider as a matter of policy whether or not its amendment proposed subsequent to the hearing will ensure adequate access in light of the concern expressed by the groups representing residents.

so amended p. 10

22. A further matter was raised by the Careview Home (Ex. U, p. 1) and the administrator of the Retirement Center of Wright County (Tr. pp. 95-97), and was also mentioned earlier by the Broeker firm. They stated that it is a common situation that a resident is not competent to designate a person to have access to his funds. The resident may also lack a legal representative. What commonly happens is that a family member is allowed access to the funds. However, the commentors are concerned that under the rule, as proposed, this would not be possible and might result in a correction order for a facility. The appointment of a legal guardian or conservator merely for the purpose of allowing access to patient funds is certainly not reasonable for most people. Although this problem is not one which is capable of an easy solution, it is one that should be addressed by the Department.

23. Section 1.048 A.8.c.(4)(b) requires that a written quarterly accounting of patient fund transfers be provided. The FRNHR supported the subsection, while the NHRAC and the Board on Aging urged that the rule specify that the statement be itemized so as to indicate individual deposits and withdrawals. (Ex. O, p. 2; Ex. M, p. 5; Ex. EE, p. 1) St. Benedict's Center suggested that since a quarterly accounting would be time-consuming, it should be provided only upon request. (Ex. K, p. 1) The NHRAC also suggested that the

word "given" be substituted for the word "provided" to ensure that the statement is received by the proper person. (Ex. EE, p. 1) The Department agreed to this suggestion. (Ex. 17, p. 5) The Department stated, however, that a specific designation as to the contents of the quarterly statement is not necessary, and believes that facilities should be able to provide information on the statements appropriate to the needs of the residents. Since the rule also limits access to the patient fund account as a safeguard, the Department believes that an itemized statement should not be mandated. (Ex, 17, p. 5) The rule, as proposed, is needed and reasonable.

24. At the hearing, the Department offered an amendment to Section 1.048 A.8.c.(4)(c)(ii) as originally proposed which would make the proposed language more specific and would result in a rule which reads as follows:

> The name of all individuals, other than the patient or resident, who have been authorized, in writing by the patient or the resident or the patient's or resident's guardian or conservator, to withdraw or expend funds from the patient's or resident's personal account. (Ex. 13, p. 1; Ex. 17, p. 1)

As amended, the proposed rule subsection is needed and reasonable.

25. Section 1.048 A.8.c.(4)(c)(iii) requires that the written records in regard to patient funds specify the date and amount of all withdrawals and, as originally proposed, requires a receipt for purchases made with patient funds. St. Benedict's Center (Ex. K, p. 1) and the Careview Home (Ex. U, p. 1) noted that requesting a receipt from a family member, for example, causes resentment and does not necessarily prevent abuse. The MAHCF and the Broeker firm (Tr. p. 87; Ex. FF, p. 5; Ex. GG, p. 12) noted that the facility cannot compel receipts to be provided, and suggested that House File 729, which was passed by the 1980 Legislature and which makes misuse of funds theft, is a sufficient deterrent to abuse. The Broeker firm stated that the Statement of Need does not support the receipt requirement. In its post-hearing comments, the Department proposed that the last sentence of this subsection be deleted. The Department believes that the other safeguards provided in the rule and the requirements of Minn. Stat. § 256B.35, as amended, provide sufficient control over the unauthorized use of funds. With the deletion, the proposed subsection is needed and reasonable.

26. Section 1.048 A.8.c.(5) requires patient funds in excess of $100 to be deposited in a trust demand account in an insured financial institution. The Department stated that the rule is necessary to assure the safety of patient funds. (Ex. 10, p. 29) Several comments (Ex. O, p. 1; Tr. p. 83; Ex. EE, p. 1) prefer that the funds be required to be in an interest-bearing account at least where the amount was over $150. The Department of Veterans Affairs (Ex. S) stated that Minn. Stat. § 198.265 requires them to deposits residents' funds with the State Board of Investment. In response to this last concern, the Department suggested that the first sentence be amended to read as follows:

> Unless otherwise specified by law, the personal funds of any patient or resident in excess of $100 shall be deposited in a demand account in a financial institution authorized to do business in Minnesota, the deposits of which are federally insured. (Ex. 17, p. 5)

The Broeker firm stated that this subsection is a major change, and that the Department's presentation is insufficient to constitute an affirmative presentation of facts. (Ex. GG, pp. 12, 14) Although the Department's presentation is minimal, the advantage to the resident of having his funds in excess of $100 in a checking account as opposed to being kept at the facility is apparent. The rule subsection, as amended by the Department's post-hearing comments, is needed and reasonable.

27. Section 1.048 A.8.c.(6) permits a facility to deposit personal funds in an interest-bearing account, and then requires that the interest be pro rated to each patient. The Board on Aging and the NHRAC (Ex. M, p. 4; Ex. EE, p. 1) again supported requiring interest-bearing accounts since residents have little money and since the proposed federal regulation would require it. The MAHCF commented that it is very difficult to pro rate interest, and that this requirement should be amended since it will discourage use of interest-bearing accounts. (Tr. pp. 89-90; Ex. FF, p. 5) The Broeker firm urged that the word "attributable" should be further defined to specify a time period or date. (Ex. GG, p. 14) The Department stated that mandating the use of interest-bearing accounts would not provide any additional safeguard which is the purpose for the proposed rule. (Ex. 17, p. 6) The rule is needed and reasonable as proposed; however, the agency should consider the possibility of consistency with the federal regulation and the testimony of residents groups that interest-bearing accounts are needed. no change p. 11

28. Section 1.048 A.8.c.(7) requires the facility to return the patient's funds upon request during time periods set by the facility and requires funds kept outside of the facility to be returned within three banking days. At the hearing, the Department proposed that this rule subsection be clarified by rewording the second sentence so that it would read as follows:

> The nursing home or boarding care home shall develop a policy specifying the period of time during which funds can be withdrawn on each day of the week. (Ex. 13, p. 1)

so amended p. 11

Three commentors suggested that access for withdrawals should be during normal business hours, or should at least have a minimum number of hours. (Ex. M, p. 5; Tr. p. 83; Ex. EE, p. 1) The Department believes that the facility is in the best position to develop a policy responsive to the needs of residents in this instance. (Ex. 17, p. 2, 6) The Broeker firm indicated that it believes that the justification for the three banking days' provision is inadequate. (Ex. GG, p. 12) The rule subsection is needed and reasonable as amended. amended p. 11

29. Section 1.048 A.8.d. provides that when a patient is discharged, personal funds shall be returned to him, and where the funds are outside of the nursing home, they shall be returned within three banking days. The Department of Veterans Affairs states that the three banking days' requirement would be extremely difficult to accomplish if the funds are on deposit with the State Board of Investment. (Ex. S) The Broeker firm commented that the Department had not justified the three banking days' provision, and observed that five working days had been discussed before the Nursing Home Advisory Council. (Ex. GG, p. 12) Although the subsection is needed and reasonable as

proposed, the Department may wish to consider whether a change in regard to the number of banking days would result in a more workable rule.

30. Section 1.048 A.8.e. provides for the return of patient funds upon the death of a patient, and ends with the phrase "and shall return the funds to the appropriate individuals in accordance with state law". The MAHCF suggested that the language quoted be deleted since it is not necessary. (Tr. p. 90; Ex. FF, p. 6) The Department agreed to this suggestion. (Ex. 17, p. 6) With the deletion, the proposed rule subsection is needed and reasonable.

31. Section 1.048 A.8.f. provides that when a facility changes ownership, a written verification by a public accountant in regard to patient funds must be provided to the new licensee. The NHRA and the NHRAC (Tr. p. 84; Ex. EE, p. 2) felt that this verification should also be provided to residents. The Broeker firm pointed out that this proposed amendment suffered from vagueness since it was uncertain what should be included within a "verification" since this is not a term familiar to accountants. Furthermore, the term "public accountant" might be taken to exclude a CPA. (Tr. pp. 102-3; Ex. GG, p. 14) The Department agreed that the rule was undesirably vague and has proposed to withdraw this particular section since the changes it would wish to make are substantial.
(Ex, 17, p. 6)

Proposed Amendment to 7 MCAR § 1.046 L. - Use of Oxygen

32. This rule is proposed to be amended to permit the use of oxygen in nonemergency situations and to set up the procedures to be followed. The amendment, as proposed, received specific support. (Ex. Y, p. 1) Concern was expressed that since the use of oxygen sometimes means restrictions upon the patient, that patients still be allowed to participate in normal activities. (Tr. pp. 114-116; Ex. EE, p. 1) The Department noted that existing rules require that individual patient's plan of care be developed and revised to meet the individual needs of a patient. St. Benedict's requested that the Director of Staff Development be an alternative to the Director of Nursing in regard to training for administration of oxygen. (Ex. K, p. 1) The Department replied that the Director of Nursing is the proper person to be ultimately responsible. (Ex. 17, p. 7) The Broeker firm stated that it was not clear that Section 1.046 L.1.a. through d. also applied to nonemergency use of oxygen. (Ex. GG, p. 15) Although Section 1.046 L.2.c.(4) would seem to incorporate those requirements into the nonemergency section, it would probably be clearer should the first sentence of 46 L. read, "1. Oxygen, may be used in a nursing home on an emergency or nonemergency basis." The Broeker firm also requested that an emergency be defined so that the nursing home can determine when to apply the nonemergency part of the rule. (Tr. p. 117; Ex. GG, p. 15) The Department stated that the requirements of Section 2 need not be met until such time as a facility admits patients in need of oxygen as reflected in the written order of the physician and, therefore, such a definition is not necessary. (Ex. 17, p. 7) At the hearing, the Department proposed that a number "3" also be added to the new language in this proposed rule amendment, which would read as follows:

3. All oxygen used in the nursing home shall be from cylinders which bear labeling indicating that the oxygen is for medical purposes.

The rule, as amended, is needed and reasonable.

Proposed Amendment to 7 MCAR § 1.047 A. - Tuberculosis Testing of Employees

33. This rule is amended to continue testing of employees for tuberculosis, but to minimize the use of chest x-ray and to eliminate the annual requirement for testing of those employees who show a negative tuberculin test. Although the Broeker firm suggested that there were insufficient facts shown to support continued testing of employees for TB (Ex. GG, p. 16), the Department stated that 42.3% of the 175 cases of tuberculosis in 1978 occurred in individuals over age 65. Screening of nursing home residents and staff, therefore, is still recommended by the Department's tuberculosis screening unit, and is consistent with the recommendations of the American Thoracic Society and the Center for Disease Control. (Ex. 10, pp. 17-18; see also, Tr. pp. 127-28) Since the Department is merely amending the rule to provide different procedures, it is not required to establish once again the need for tuberculosis testing.

34. A new requirement in the rule is that the nursing home and boarding care home reimburse their employees for the costs of the tests required in the rule. The MAHA and the Broeker firm suggested that there was no rationale or facts presented to justify the facilities paying these expenses and urged deletion of the requirement. (Ex. J, p. 2; Tr. p. 126; Ex. GG, p. 16) The only rationale for this change provided by the Department was a single sentence in the Statement of Need which stated that, "Because the facility is responsible for assuring the testing, it is reasonable to require the nursing home to provide the testing or to reimburse its employees for the costs of obtaining the tests." (Ex. 10, p. 18) It does not appear that it necessarily follows that facilities should bear the costs merely because they are responsible for seeing that the testing is completed. Although it may very well be within the Department's statutory authority to promulgate this rule if it can be demonstrated that it is related to the welfare of patients, no facts or argument has been presented which would demonstrate that to be true. Accordingly, the Department has failed to make an affirmative presentation of facts showing the need for and reasonableness of requiring the facilities to pay the costs of tests.

35. Section 1.047 A.1. requires all employees to have a tuberculin test within 45 days prior to employment, unless a physician certifies a positive reaction. Two comments question the 45-day period as being unrealistic. (Ex. K, p. 1; Ex. Y, p. 1) The Department stated that a 45-day period is necessary due to the time delay from the time of infection to the point at which a skin test can identify an infection. (Ex. 17, p. 8) Two other comments (Ex. U, p. 1; Ex. CC, p. 2) questioned why a physician certification is necessary if an employee knows that he has a positive reaction. Dr. Terrence Henderson suggested that a statement of a past employer that the employee has a positive

reaction should be sufficient. The Department stated that a doctor certification prevents an employee, who is mistaken in his belief that he is a positive converter, from undergoing unnecessary x-rays and other tests. This rule subsection is needed and reasonable as proposed.

36. Section 1.047 A.1.b. requires that where the tuberculin test is positive, the employee must annually submit a report by a physician of a negative chest x-ray for five years. Dr. Henry B. Blumberg commented that the need for annual chest x-rays should be a matter for the individual personal physician to decide. (Ex. CC, p. 1) Dr. Terrence Henderson suggested a three-year limit for the chest x-rays in light of new knowledge concerning adverse effects of overexposure to x-rays. (Ex. CC, p. 3) The Department may consider these suggestions; however, the subsection is needed and reasonable as proposed.

no change p.6

Proposed Amendment to 7 MCAR § 1.049 C.1. - Patient Tuberculosis Screening

amendments withdrawn. see F.F 1n

37. The Department proposes to amend this rule to require a chest x-ray within 45 days prior to admission for all patients. The existing rule requires a tuberculin test or if that test is positive, a chest x-ray within three months of admission. The Department states that the chest x-ray is substituted as the initial test upon the recommendation of the American Thoracic Society and the Center for Disease Control because an older person is less able to respond accurately to a tuberculin skin test. (Ex, 10, p. 22) Two comments (Ex. D; Ex. Y, p. 1) favored keeping the three-month provision. Dr. C. Dwight Townes noted that the Department's amendment is in line with the American Thoracic Society recommendation. (Ex. H) The Hazelden Foundation, which operates a 22-bed nursing unit, cited the increased expense and the hazard of x-rays as reasons for not promulgating this amendment. (Ex. T) The MAHCF pointed out that the patient bill of rights allowed a patient to refuse an x-ray and suggested that language be added to recognize this. (Tr. pp. 122-125) The Careview Home also cited the cost of the x-ray and questioned the need for a change from the tuberculin test. (Ex. U, p. 2) The Broeker firm questioned whether or not the Department had adequately supported its amendment.

38. An official statement of the American Thoracic Society in regard to screening for tuberculosis in institutions was attached to the Statement of Need as Exhibit D. The Statement notes that older persons admitted to nursing homes for long-term care have a higher prevalence of tuberculosis than the general population, and the institutional setting with persons grouped together increases the possibility of transmission of tuberculosis infection. The Statement also says that because there is a waning of tuberculin sensitivity with advancing age, the tuberculin test is not recommended as the initial screening test for older age groups. The Broeker firm suggests that the Department has not presented facts relating to the experience in the State of Minnesota, although the Statement of Need does indicate that 42% of the active tuberculosis cases in Minnesota in 1978 were in persons 65 and over. The statement of the American Thoracic Society says that screening programs should

be based on local data. It states that, "To determine the appropriate organization of the screening program in a given institution, it is necessary to know the incidence and prevalence of tuberculosis and tuberculosis infections in personnel and in persons served both in the institution and in the community from which they come. Data generated by the screening program should be used to evaluate and modify the program." The Department has not presented any data or argument to indicate that the tuberculin test has been ineffective or that the incidence of tuberculosis among nursing home personnel and residents in Minnesota would justify such a change. The Department has failed to adequately demonstrate the need for and reasonableness of this proposed change.

Proposed Amendment to 7 MCAR § 1.048 A.4. - Storage and Preservation of Records

39. The Department proposed to amend the period for retention of patient records following discharge or death from 10 years to five years. The Department stated that the 10-year period was unnecessary and burdensome in light of a lack of storage space in most facilities. (Ex. 10, p. 24) The amendment was supported by the MAHCF and the MAHA (Ex. FF, p. 6; Ex. J, p. 3) and others. (Ex. G) The Minnesota Medical Record Association pointed out that records are valuable in the study of geriatrics and chronic disease. (Tr. pp. 134-7) They recommended that the period be set at six years to coincide with the six-year statute of limitations in regard to contract actions. The examples cited by the Association, however, namely suits for injury or death resulting from an accident would appear to fall under the two-year statute of limitations at Minn. Stat. § 541.07, rather than under the contract statute of limitations at Minn. Stat. § 541.05. The proposed amendment has been shown to be needed and reasonable.

Proposed Amendment to 7 MCAR § 1.052 A.1. - Patient and Resident Units

40. This rule is proposed to be amended to eliminate the prohibition against the use of double beds and to require the facility to develop a written policy in regard to double beds. The LCRAR recommended suspension of the prohibition against the use of double beds. (Ex. 10, p. 31) The MAHCF supported the amendment. (Ex. FF, p. 6) The Careview Home questioned whether any rule or policy was needed in this area. (Ex. U, p. 2) The proposed amendment is needed and reasonable.

Proposed Amendment to 7 MCAR § 1.053 F. - Medications

41. This rule is proposed to be amended to conform with Board of Pharmacy Rule 7 MCAR § 8.032. The amendment to this rule will delete the mandatory destruction of unused drugs and permit their return to the dispensing pharmacy in accord with the Board of Pharmacy rule. The concept of eliminating the mandatory destruction of drugs was supported by Dr. Townes (Ex. H), Dr. M. L. Lohmann and Mrs. J. D. Ingersoll (Ex. X), Br. Henderson (Ex. CC, p. 3) and the Pelican Lake Nursing Home. (Ex. Y, p. 1) The MAHA stated that the number of forms to be submitted could be limited by limiting the requirement to Schedule 2, 3, and 4 controlled substances. (Ex. J, p. 4; Tr. pp. 138-9) This would

apparently require a change to the Board of Pharmacy rule. The amendment is needed and reasonable as proposed.

Proposed Amendment to 7 MCAR § 1.055 U. - Dishwashing

42. This amendment is proposed to eliminate the prohibition against chemical sanitizing for dishwashing. In March of 1979, Economics Laboratory, Inc. submitted a formal petition for rulemaking in regard to the use of this type of dishwashing machine. The Department states that changes in technology have made low temperature dishwashing safer and acceptable for nursing homes. The MAHCF suggested that the first paragraph be amended to make it clear that either hot water or chemical sanitizing was permissible. (Ex. FF, p. 7) The Department agreed and suggested that the words "either of" be inserted after the words "shall conform with" in the first paragraph. (Ex. 17, p. 10) inserted p.16

43. In regard to Section 1.055 U.1.b.(1)(a), Economics Laboratory, Inc. suggested that the word "approved" was not appropriate. (Ex. P, p. 2) The Department agreed to rephrase the subsection to read as follows:

> Dishwashing machines using chemicals for sanitizing shall bear the seal indicating that the machine meets the standards of the National Sanitation Foundation. (Ex. 17, p. 10)

changed p.16

So amended, the proposed subsection is needed and reasonable.

44. 7 MCAR § 1.055 U.1.b.(1)(b) requires an audible signaling device when the detergent or chemical sanitizing supply is empty. Chemical Methods Associates, Inc. (Ex. E, p. 1) pointed out that a visual method should be an alternative in the rule. Economics Laboratory, Inc. stated that the National Sanitation Foundation Standard does not require a warning signal for detergent supply. (Ex. P, p. 2) The Department concurred in the suggestions and recommended that the subsection be revised as follows:

> Each dishwashing machine shall be equipped with a visual or audible signaling device which indicates when the chemical sanitizing supply is empty. The signaling device shall be maintained in an operating condition. (Ex. 17, p. 10)

revised p.16

So amended, the subsection is needed and reasonable.

45. Section 1.055 U.1.b.(1)(c) sets a pressure to be supplied for the final rinse water. Both Chemical Methods Associates, Inc. (Ex. E, p. 1) and Economic Laboratory, Inc. (Ex. P, p. 3) pointed out that all currently available commercial low temperature machines use a pump to provide a recirculating rinse and, therefore, are not dependent upon pressure of the external supply line. The Department agreed and proposed to withdraw this subsection. (Ex. 17, p. 10) withdrawn

46. Section 1.055 U.1.b.(1)(d) requires the clean dish counter to provide space for at least four racks of dishes and utensils. The Department stated that counter space is necessary to assure proper air drying which is of particular concern with chemical sanitizing since the dishes are subjected to lower temperatures and take longer to dry. (Ex. 10, p. 35) Chemical Methods Associates, Inc. commented that the primary factors in the drying rate are temperature and humidity, and that humidity is usually lower when chemical sanitizing is used. They believe that this requirement is not justifiable since it would tend to limit the use of chemical sanitizing dishwashers. (Ex.

E, p. 2) Economic Laboratory, Inc. commented that specifying the number of racks is too rigid and suggested rephrasing the rule by stating that the clean dish counter be adequate to provide a two-minute drying time per rack. (Ex. P, p. 3) Although the rule is needed and reasonable as proposed, the Department is encouraged to consider the suggestions of Economic Laboratory, Inc. so as to avoid excluding machines which fall within the spirit but not the exact language of the rule. no change see F&F 21

47. Section 1.055 U.1.b.(2)(d) sets a minimum rinse water temperature. Economic Laboratory, Inc. proposed that the term "chemical manufacturer" be changed to "machine manufacturer". (Ex. P, p. 4) The Department agreed and suggested that the subsection be reworded as follows:

> The chemical sanitizing rinse water temperature should not be less than 75 degrees Fahrenheit (24 degrees centigrade) nor less than the temperature specified by the machine manufacturer as indicated on the NSF data plate.

The subsection is needed and reasonable as amended.

48. Section 1.055 U.1.b.(2)(f)(i) requires the concentration level to be tested "each time the machine is used". Chemical Methods Associates, Inc., Economics Laboratory, Inc., and the Anoka County Director of Environmental Services (Ex. E, p. 2; Ex. P, p. 4; Ex. C, p. 1) all found the quoted phrase ambiguous and impractical if it means a test after each cycle of the machine. The Department agreed and suggested that the word "time" be replaced by the word "day". So amended, the proposed subsection is needed and reasonable. amended p. 17

Proposed Amendment to 7 MCAR § 1.064 A.3.f.(1) - Bedroom Doors

49. The existing rule prohibits locks on patient room doors. The LCRAR recommended suspension of the existing rule. The proposed amendment requires the nursing home to develop a written policy regarding locks and describes the type of lock which may be used so that for safety purposes the door can be opened from the inside at all times without a key. The Residents Council of the Halstad Memorial Home stated that they believed that locks were not necessary (Ex. B), and St. Benedict's commented that locks present a difficulty from a fire safety standpoint. (Ex. K, p. 2) The MAHCF commented that the language in B, stating that the door can be "locked only from the corridor side" might be interpreted to not permit the resident to lock the door from the inside. The Department should examine a clarification in this regard. The proposed amendment is needed and reasonable.

Proposed 7 MCAR § 1.044 X. - Variance in Waivers

50. This proposed rule will set up a procedure for granting variances and waivers which the Department believes is necessary where complete compliance with the rules is not possible. (Ex. 10, p. 4) The MAHA (Ex. J, p. 4) and the MAHCF both supported the concept of a waiver and variance rule. (Ex. FF, p. 7) The NHRAC opposed any waiver for the minimal daily dietary requirements or the patients bill of rights. (Ex. EE, p. 1) The Broeker firm and the MAHCF raised several items which they believed were not addressed in the proposed rule and should be. (Ex. GG, pp. 19-21, 23; Ex. FF, p. 7) One concern is the effect of a waiver request in a later enforcement proceeding; namely,

whether or not the request can be used to prove a violation. Another concern is whether or not a penalty may accrue even though a variance or waiver request is pending before the Department. It was also requested that should a waiver be denied, the facility should then have a period of time for correction subsequent to the denial. Both the Broeker firm and the MAHCF suggested amendments to be added to the rule which would make it clear that a request for a waiver is not an admission and that no fine would accrue while a request is pending. (Ex. FF, Amendment No. 3 and 4) Although the proposed rule is not rendered unreasonable by the failure to include these items, the Department may consider their inclusion since these are decisions which will have to be made by the Department at some point in time. As the Department points out, however, they may be enforcement decisions depending upon the circumstances of particular cases and it might also properly be the subject of later rulemaking based on the enforcement experience.

51. Section 1.044 X.2.d. requires a request for variance to include the length of time for which it is requested. Both the Broeker firm and the MAHCF suggested that the Department should consider criteria by which to evaluate the length of time or to consider when a waiver should be permanent. (Ex. FF, p. 8; Ex. GG, p. 21) The subsection is needed and reasonable as proposed.

52. Section 1.044 X.2.e. allows the Department to obtain from the applicant such other relevant information which "the Department shall determine is necessary to properly evaluate the request". The Broeker firm again raised the question of what would happen if the Department makes such a request and the nursing home is in the process of assembling the material while the time period for the correction order runs out. The Broeker firm also suggested that the possibility of an oral presentation should be included in the rule. (Tr. pp. 169-170, 172) Although the rule subsection is needed and reasonable as proposed, the Department should limit the discretion given to it in the proposed rule by eliminating the language "which the Department shall determine is" or indicating by the addition of language that only information necessary to comply with this rule may be requested. complied p. 1 and p. 26

53. Section 1.044 X.3.a. sets out the criteria for evaluation of a request. The Broeker firm and the MAHCF both noted that because of the way the rule is structured, the Department would have to make an affirmative finding in regard to each of the three criteria before a variance or waiver could be granted. (Ex. FF, p. 8; Ex. GG, pp. 21-22; Tr. pp. 155, 172) This creates a problem since alternative measures are sometimes not possible and an innovative approach to a nursing home problem might not necessarily impose an undue burden upon a nursing home. The Department agreed that the problem existed and suggested that the subsection be amended as follows:

> a. The decision to grant or deny a variance or waiver shall be based on the Department's evaluation of the following criteria:
>
> 1. The variance or waiver will not adversely affect the health, treatment, comfort, safety or well being of a patient or resident;
>
> 2. The alternative measure to be taken, if any, are equivalent or superior to those prescribed in the rule; and

3. Compliance with the rule or rules would impose an undue burden upon the applicant.

The Department believes that this proposed language will provide the flexibility to handle situations where a particular criterion is not applicable. (Ex. 17, p. 12) So amended, this subsection is needed and reasonable. so amended p. 1

54. Section 1.044 X.4. provides that alternative measures attached to a variance may be the subject of correction orders and shall have the same time period for correction as the rule for which the variance was granted. The MAHCF and the Broeker firm (Tr. pp. 157-8; Ex. FF, p. 9; Ex. GG, p. 22) stated that it was not reasonable to automatically apply to the alternative measure the same period of time for correction in the rule where the alternative measures require action that is different in scope or nature than the actions necessary to comply with the rule. The MAHCF suggested that the following language be added to the end of this subsection: "unless the alternative measures necessitate actions different in scope or nature from the actions necessary to comply with the literal requirements of the rule". (Ex. FF, Amendment No. 6) Although the subsection as proposed cannot be said to be unreasonable or arbitrary, the Department should consider the addition of some language similar to that proposed by the MAHCF so that a time period and fine appropriate for the violation is arrived at. no change p. 2

55. Section 1.044 X.5.a. requires a request for renewal of a variance to be in writing and submitted prior to the expiration of the variance. The MAHCF suggested that the rule is too rigid since it does not provide for the situation where a facility finds out the day before the expiration of its variance that it cannot apply. (Tr. pp. 159-61; Ex. FF, p. 9) They suggested deleting the phrase "prior to its expiration date" so that a request could be submitted after expiration. The Department stated that this requirement is necessary to be informed as to the continued need for a variance. (Ex. 17, p. 13) Enforcement would be difficult if a facility was able to request renewal at any time after expiration. The subsection is needed and reasonable as proposed.

56. Section 1.044 X.5.b. provides that the variance may be renewed if the criteria continues to be satisfied and the applicant continues to comply with alternative measures or conditions imposed. At the hearing, the Department proposed to replace "may" with "shall". (Ex. 13, p. 1) The Broeker firm questioned how the applicant was to demonstrate compliance with alternative measures and stated that the vagueness in this phrase rendered the rule unreasonable. (Ex. GG, p. 23; Tr. pp. 173-175) The Department stated that what it seeks is assurances in terms of what the facility has done to specifically comply with the alternative measures. (Tr. pp. 174-175) The subsection is needed and reasonable as proposed and amended. amended p. 2

57. Section 1.044 X.6. provides that an applicant shall be notified in writing of a decision to deny, revoke or refuse to renew a variance or waiver. The MAHCF and the Broeker firm stated that it was necessary that the reasons for the denial be stated by the Department and also stated that a time limit should be set by which the Department must make its decision. (Tr. pp.

161-162; Ex. FF, p. 9; Ex. GG, p. 23) The Department agreed as to the need for a statement of reasons and suggested that the last sentence read as follows:

> The applicant shall be notified in writing of the decision to deny, revoke or refuse to renew the variance or waiver, informed of the reasons for the denial, revocation or refusal to renew, and informed of the right to appeal this decision. (Ex. 17, p. 13)

The Nursing Home Advisory Council had suggested a 30-day time limit which the MAHCF suggests is particularly necessary if a request for a waiver does not stay the accrual of fines. Although the proposed subsection is needed and reasonable as amended, the Department should consider the inclusion of a time period for decision in order to make the the entire waiver rule more workable.

58. Section 1.044 X.7. sets out the appeal procedure and provides that the applicant must appeal within 15 days of receipt of the Department's decision and places the burden of proving that it has satisfied the criteria upon the applicant. The MAHCF commented that the 15-day period was too short and suggested that a 20-day period be substituted. (Tr. p. 163) The Broeker firm questioned whether or not the burden of proof ought to be placed on the applicant. (Ex. GG, p. 23) The Department replied that this is appropriate since the applicant is in the best position to demonstrate that the criteria have been met. The Department cited the case of In re Application of the City of White Bear Lake, 247 N.W.2d 901, 904 (1976) as authority for the proposition that generally an applicant has the burden of proof. The Department accurately states the law except in regard to the revocation of a variance or waiver. Generally the proponent of certain action being taken is the party which has the burden of proof, and generally when an agency seeks to revoke a license, a permit or a waiver which it has granted, it will then have the burden of proof. See, 1 Cooper, State Administrative Law, Ch. 12, § 1 (1965). The Department should amend this section to exclude the revocation situation from the general rule as to the burden of proof.

Proposed Amendment of 7 MCAR § 1.057 A., B. and C. - Schedule of Fines

59. Section 1.057 C. sets out the schedule of fines for the other rules which are being promulgated in this rule hearing proceeding. The fines accrue daily in accordance with Minn. Stat. § 144A.10, subd. 6, which provides that a nursing home "shall be assessed a civil fine in accordance with the schedule of fines promulgated by rule of the Commissioner of Health. A 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. . . ." The Department has authority to assess fines up to $250 per day, and has divided the schedule of fines into three levels of assessment at $50, $150 and $250. The three levels are based on the degree of harm that would result if the nursing home fails to comply with the rule in question. The Department stated that:

> A $50 penalty assessment will be issued for a violation of these rules which have only a minimal relationship to the health, safety, treatment, comfort or well being of a patient in the nursing home. A violation of these rules would not create a

situation which would jeopardize the health or safety of a patient. A $150 penalty assessment will be issued for a violation of those rules which could potentially create a situation jeopardizing the health, safety, treatment, comfort or well being of the patient. A $250 penalty assessment will be issued for a violation of these rules which would create a situation jeopardizing the health, safety, treatment, comfort or well being of the patients. (Ex. 10, p. 40)

At the hearing, the Department proposed adding one more rule subsection to C.2. of the rule to read as follows:

Z. 7 MCAR § 1.046 L.3. (Ex. 13, p. 1)

inserted on p. 20 as C.2.f.

The proposed rule including the provisions for three levels of fines, daily fines and a $50 minimum fine were supported by the FRNHR (Ex. BB), the Metropolitan Senior Federation (Tr. pp. 232-4) and the Minnesota Board on Aging (Tr. pp. 235-6). The MAHCF and the Broeker firm each stated that a $50 per day fine was too high for a violation which only minimally affects the health or safety of a patient. (Tr. pp. 192-195; Ex. GG, p. 24) They stated that the Department had failed to justify the reasonableness of the $50 minimum fine as opposed to a system which permits either a more flexible assignment of fines or a fixed daily fine less than $50. The Department pointed out that a recent Hennepin County District Court decision found the mandatory predetermined administrative fine constitutional and suggested that it in fact avoided some problems since it maintained uniformity and avoided discrimination. (Ex. 16) The Department also stated that violations which have a minimal relationship to patient health or safety does not necessarily equate to a de minimus violation in the OSHA area, as was suggested by the MAHCF. (Tr. p. 202) The Department's position is that the three levels including the $50 minimum per day fine provide a rational basis for the issuance of assessments, especially since prior to the issuance of a fine, the nursing home is fully informed as to the nature of the deficiencies and provided a period of time in which to make the necessary corrections. Only where a facility has failed to comply with the correction order and, where upon reinspection the Department determines the facility is still in noncompliance will a fine then be assessed. (Ex. 10, p. 40) The proposed rule has been demonstrated to be needed and reasonable.

60. The MAHCF and the Broeker firm raised several other important questions relating to the operation of this rule and the statute. (Ex. FF, pp. 10-20; Ex. GG, p. 24) The most serious issue raised is the question of whether or not fines continue to accrue on a daily basis in regard to an assessment when an appeal has been taken and not yet decided. The Broeker firm and the MAHCF believe that if this is the Department's interpretation, then the system is unconstitutional since there is no opportunity for a hearing before the fine, and the daily penalty is so burdensome in its cumulative effect that a facility is effectively permitted from appealing the matter. The MAHCF believes that the statute does not mandate daily accrual of fines based on the interpretation that a facility is not in violation or in noncompliance unless it has failed to appeal or appealed an assessment and lost. (Ex. R) Another remedy proposed by the MAHCF would be that the Department allow an appeal from the issuance of a correction order prior to the assessment of a fine.

61. Although the facility raised serious questions in regard to the procedure to be followed, a careful consideration of all of the materials submitted leads to the conclusion that the MAHCF's dispute is with the statute rather than the proposed rule. The statute mandates a daily fine. The only provision in the statute for a stay of an assessed fine is in regard to its recovery rather than in regard to its accrual. Minn. Stat. § 144A.10, subd. 6 through 8 appears to contemplate the accrual of fines during an appeal and it would appear to be questionable whether the Department could properly promulgate a rule which provided otherwise. The constitutionality of the system which is established by the statute in regard to correction orders, inspections and fines of nursing homes must be resolved by a court of law. The matter has already once been the subject of litigation. The proposed rule is not unreasonable by reason of its failure to speak to the matter of accrual of fines during an appeal since the question is answered by the statute.

7 MCAR § 1.058 - Allowable Time Periods for Correction

62. This is a new rule proposed by the Department to satisfy the statutory mandate to establish a schedule of allowable time periods for correction of deficiencies. The rule will apply only to the rules which are being promulgated in this rulemaking proceeding. The Department offered three amendments at the hearing; namely, adding the following to Section 1.058 A.1.:

g. L.3. 30 days

and in regard to Section 1.058 A.7.c., changing the 14 days to 30 days and correcting a typographical error in Section 1.058 B.3.a.(2)(a) in the word "supplies". (Ex. 13, p. 1; Ex. 17, p. 2) The allowable time periods for correction were divided by the Department into three categories; namely, 14 days, 30 days and 60 days. The 14-day period is used for those rules which can be easily corrected by a facility utilizing the internal resources of the nursing home such as those orders which can be corrected by the development of internal policies. The 30-day period is utilized for those rules that were possibly capable of being corrected through the utilization of nursing home resources, but would usually require some contacts with individuals outside of the facility. A 60-day time limit is reserved for those specific rules where outside resources would generally have to be contacted such as the purchasing of equipment or the obtaining of contracts. The Department notes that where the nursing home can demonstrate that the time period is not sufficient, it can request an extension from the Department. (Ex. 10, pp. 55-57)

63. The MAHCF suggested that these time periods should be minimums only and suggested that language be added to the first paragraph of the rule permitting the surveyor to set a longer period where he finds unique circumstances. (Ex. FF, p. 20) The Broeker firm stated that the Department's presentation did not contain any experience, facts or alternatives to support the assignment of the different periods to various rules. (Ex. GG, p. 30) More specifically, they suggested that a change in internal policies may require more than 14 days where a patient care committee must be convened and also that violations of the dishwashing rules may require outside help and

therefore require more than 14 days. (Tr. p. 257-63) The Department has adequately demonstrated the need for and reasonablenes of Section 1.058 A. Although the Department has not discussed individual instances of its experience with the time periods for correction in the past, it would appear that the reasoning and conclusions contained in the Statement of Need are necessarily based upon that experience.

64. Section 1.058 B.1. provides that the nursing home administrator may request an extension which must be received by the Department prior to the expiration of the time period for correction. The MAHCF suggested that requiring that the request be received prior to the expiration of the time period in the correction order would encourage unnecessary filing by facilities. They propose that the last two sentences of the rule subsection be deleted. (Tr. p. 250; Ex. FF, p. 21) The Broeker firm stated that the failure to submit a request within the time period should not always automatically result in a denial and should be subject to a good cause exception. The firm also saw a need for a period of time after denial to allow for correction. (Tr. p. 267; Ex. GG, pp. 30-31) The Broeker firm also suggested that the rule should state that persons other than the administrator can request the extension. (Tr. pp. 263-64)

65. In response to the last suggestion, the Department suggested that the words "administrator of" be deleted from the proposed rule subsection so that "the nursing home" requests an extension. The Department stated that the automatic denial upon a failure to timely request an extension is necessary to assure prompt compliance by facilities. (Ex. 17, p. 16) It is a mechanism to assure that facilities will not delay in making efforts to attain compliance based on an assumption that they could always request an extension at some time in the future. The subsection is, as amended, needed and reasonable.

p.23

66. Section 1.058 B.2.a.(6) provides that the Department can request "such other relevant information which the Department shall determine is necessary". The prior comment in regard to this type of language at Finding of Fact No. 51 should apply here also.

67. Section 1.058 B.2.b. requires that an oral request for extension be confirmed in writing within 24 hours. The Broeker firm suggested that the requirement should be one working day so as to avoid a problem with weekends. (Ex. GG, p. 31) The Department may consider this request; although, since the rule as proposed appears to merely require the administrator to place the written request into the mail, it is needed and reasonable.

68. Section 1.058 B.5. provides that the Department shall give its reasons for denial of any request for extension in writing. The MAHCF suggests that the denial of a request for extension will give rise to a contested case under Chapter 15 and that the rule should so state similar to the appeal procedure in the variance and waiver section. It has suggested proposed language which would require an applicant to submit a written request for hearing within 15 days of the receipt of the denial. (Ex. FF, Amendment No. 12) Although the proposed rule is not arbitrary for a failure to set out the requested language, the Department may consider its inclusion. The subsection is needed and reasonable as proposed.

69. General support of all of the proposed rules was expressed by the Executive Director of the Legislative Commission to Review Administrative Rules (Tr. pp. 59-60), and by the Metropolitan Senior Federation (Tr. p. 67)

Based upon the foregoing Findings of Fact, the Hearing Examiner makes the following:

CONCLUSIONS

1. That the Department of Health gave proper notice of the promulgation of the proposed rules and rule amendments.

2. That the Department of Health has statutory authority to promulgate the proposed rules and rule amendments.

3. That the Department of Health has, with the exceptions noted at Findings of Fact Nos. 52, 58 and 66, fulfilled all relevant substantive and procedural requirements of law or rule.

4. That the Department of Health, with the exceptions noted at Findings of Fact Nos. 34 and 38, has demonstrated the need for and the reasonableness of the proposed rule amendments by an affirmative presentation of facts in the record.

5. That a finding of need and reasonableness or compliance with Chapter 15 in regard to any particular rule amendment should not preclude or discourage the Department from further modification of the language based upon an examination of the public comment, provided that no substantial change is made from the rules as originally proposed and provided that the rule finally adopted is based upon facts appearing in the record.

Based upon the foregoing Conclusions, the Hearing Examiner makes the following:

RECOMMENDATION

It is recommended that the proposed rule amendments be adopted as modified by the Findings of Fact and Conclusions set out herein.

Dated: May 20 , 1980.

GEORGE A. BECK
State Hearing Examiner

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes

STATEMENT OF NEED AND REASONABLENESS

The statutory authority of the Department of Health to promulgate these rules is contained in the provisions of Minnesota Statutes §§ 144.56, 144A.08 and 144A.10 (1978). Minnesota Statutes § 144.56 and 144A.08 (1978) provides the Commissioner of Health the authority to establish minimum standards to assure for the health, treatment, comfort, safety and well-being of patients and residents in boarding care homes and nursing homes. Minnesota Statutes § 144A.10 (1978), which applies to nursing homes only, requires that the Commissioner of Health establish, by rule, a schedule of allowable time periods for correction of nursing home deficiencies (Subdivision 4) as well as a schedule of fines for non-compliance with correction orders (Subdivision 6).

This hearing is being conducted in response to the request made by the Legislative Commission to Review Administrative Rules (LCRAR) in a letter to Commissioner Pettersen, dated February 4, 1980 (a copy of this letter is attached as Appendix A). The LCRAR specifically requested that the Department propose new rules to address the following issues: the use of oxygen; tuberculosis testing of employees and of patients and residents; disposition of medications; record retention; patient and resident funds; and variances and waivers. Each of these issues has been addressed in the proposed rules. The LCRAR also recommended the suspension of the rules prohibiting the use of double beds and locks on patient bedroom doors. The Department has decided to repeal these provisions as part of this rule-making proceeding. The

Department has also developed a proposed rule which would permit the use of low temperature/chemical sanitizing dishwashers, a subject that was singled out for possible revision by the LCRAR. To comply with the provisions contained in Minnesota Statutes § 144A.10, relating to the issuance of correction orders and penalty assessments, a schedule of allowable time periods for correction and a schedule of fines which provides for the accumulation of fines on a daily basis are proposed regarding the rules being promulgated at the present time.

Under the provisions of Minnesota Statutes § 3.965, subdivision 3, the LCRAR has the authority to require that state agencies hold a public hearing to carry out their recommendations. This statute requires that the public hearing be held within 60 days of the receipt of the LCRAR's request. When the filing deadlines for printing material in the State Register are considered, the time available for actually developing the rules was extremely limited. However, since the Department is in the process of generally revising the existing nursing home rules, a number of drafts were available upon which to base these proposed rules. Due to the limited amount of time that was available, the Department was unable to submit the final draft of the proposed rules to the Nursing Home Advisory Council, which was created in accordance with the provisions of Minnesota Statutes § 144A.17. However, the Advisory Council had previously completed their review of the drafts upon which portions of the proposed rules were based. The Advisory Council also had the opportunity to comment on almost all items being proposed. Thus, the Department developed the proposed rules with the benefit of the recommendations of the Advisory Council.

A copy of the Notice of Intent to Solicit Outside Opinion published on November 8, 1976 (1.S.R. 741) is attached as Exhibit B.

A copy of the written materials received in response to that Notice are attached as Exhibit C. However, it should be noted that only a portion of this material is pertinent to the rules being promulgated at this time since issues relating to the overall revision of the nursing home rules are also addressed.

In accordance with the provisions of Minnesota Statutes § 144A.29, subdivision 4, (1978) a short statement of the anticipated costs and benefits to be derived from the provisions of the rules is attached.

7 MCAR § 1.044 X. Variances and Waivers

I. General

The authority to propose a rule permitting the granting of a variance or waiver from the licensing rules is inherent in the Department's authority to promulgate rules. The Department recognizes the need for some uniform method to grant variances or waivers from the rules since situations occur where total compliance with the provisions of the rules would not be possible. Since the adoption of the existing rules in 1972, the Department has often been requested to grant a variance or waiver from the rules. However, without a specific rule in this regard and without an established mechanism to review these requests, it was not within the Department's authority to grant a variance or waiver.

The requests for a variance or waiver will generally be considered in those situations in which a particular rule would not be relevant or in situations where compliance with the literal requirements of the rule would impose an undue hardship. However, a request for a variance or waiver could also be considered in those situations in which a new and innovative approach to long term care is being recommended which might not necessarily strictly comply with the requirements contained in rule.

Thus, as part of the general revision of the nursing home rules the Department recognized the need to develop a mechanism to review requests for the granting of variances and waivers. The Department believes that this proposed rule establishes a reasonable mechanism for the processing of these requests. The Department, while aware of the difference between a variance and a waiver, does not feel that it is necessary to differentiate these differences in the rule. For the purpose of this rule, the Department considers a "variance" to mean the granting of permission to

comply in a manner other than that specified in the rule; while a "waiver" would mean the granting of permission not to comply with the provisions of a rule. However, these two terms are generally confused with one another and since the procedures governing the request and processing would be identical, the Department felt that it would eliminate confusion by not detailing the differences. In each situation, a request for a variance or a waiver is, in fact, a request not to be required to follow the literal language of the rule. Thus, a technical definition was felt to be of little importance to this rule.

The proposed rule establishes that process for the request of the variance or waiver and specifies the type of information that is to accompany these requests. The rule also contains the criteria against which the request will be evaluated and indicates the procedures for granting or denying the request and the imposition and effect of any alternative measures or conditions that would be required if a variance or waiver was granted. In addition, the proposed rule establishes the procedures for renewals and appeals.

II. Specific Analysis of the Rule

Section 1 - General Provisions

This rule simply states that the nursing home or boarding care home has the right to request a variance or a waiver. This section does not place any limitations as to the particular rule or rules for which a variance or waiver would be considered.

Section 2 - Contents of Request

The rule specifies that all requests for a variance or waiver are to be in writing and details the information that is to be provided at the time of the request.

The requirement that the request be submitted to the Department in writing is obvious, since a written record will be needed for a careful consideration of the request. In addition, the written request will furnish a record for the Department and will be available to the public for their review. Each request is to contain five elements. The first is the requirement that the specific rule or rules be identified. This is necessary to assure that the request is correctly analyzed in context with the appropriate rules. The requirement is reasonable to assure that the granting or denial of the request makes reference to the appropriate rule. The second element is an explanation of the reasons for the request. Since the rules adopted by the Department are only minimum standards, there is an underlying assumption that strict compliance with the rules is reasonable. The granting of a license to operate a nursing home or boarding care home is premised upon the facility's agreement to comply with these minimum standards. Thus, it is reasonable for the Department to request that the facility detail the reasons for seeking a variance or waiver. The facility should indicate why there are problems in complying with the established minimum rules, and, if applicable, the facility should indicate what steps had been taken to attain compliance and why those steps were not successful. The reasons for the request will also provide a basis upon which to determine whether compliance with the rule would create an undue burden on the facility. The third element is to outline the alternative measures that would be taken if the variance or waiver is granted. Each of the licensing rules has a role in assuring that the health, safety, treatment, comfort and well-being of residents is maintained. In most situations, the facility which requests a variance or waiver will have to show that the purpose and intent of the rule will be met through the use of alternative measures. If the variance or waiver is granted, it will be these alternative measures that will assure that the purpose and intent of

of the rule is being met. Thus, to fully protect the individuals residing in the facility, it is necessary to assure that acceptable alternative measures will be taken. The Department realizes that in some situations, alternative measures would not be feasible. In these situations, the facility would simply specify that alternative measures would not be possible and explain why. The fourth element will be the facility's opinion as to how long the variance or waiver will be required. In many situations, the variance or waiver may be required to relieve the problem of complying with a rule for a limited period of time. Since the administration of the facility is in a good position to consider the length of time for which the variance is requested, this requirement is not unreasonable. The last category provides that other relevant information be supplied to the Department if additional information is necessary to properly evaluate the request for the variance or waiver. In reviewing a request it may become apparent that further information or clarification is necessary for the Department to make an informed decision. It is reasonable to require a means by which this information can be obtained.

Section 3 - Criteria for Evaluation

Section a. outlines the criteria that will be used by the Department in evaluating whether or not the request for a variance or waiver should be granted. The Department believes that the criteria provides a reasonable basis upon which to determine whether or not a variance or waiver should be issued. The first criteria is a consideration of the alternative measures that will be taken if the variance or waiver is granted. This criteria is necessary to assure that these alternative measures meet the purpose and intent of the rule. As previously mentioned, the rules prescribe only minimum standards and it is incumbent upon the Department to assure that any deviation from those minimums will result in

the substitution of acceptable alternatives. In situations where alternative measures would not be available, the Department would note this fact during their review. The second criteria parallels, to a certain extent, the provisions of the first criteria. There must be a clear decision which supports the fact that the issuance of the variance or waiver will not, in any way, adversely affect the health, treatment, comfort, safety or well-being of the patients or residents. In many situations, the review of the alternative measures will also be intertwined with the determination of the adverse effect of the variance or waiver. The Department must assure that the permission to not comply with the provisions of the rule is granted only in those situations where an adverse affect on patients and residents will not occur. This criteria is necessary to assure that the Department's responsibility to protect individuals in health care facilities is not diminished, and it is reasonable to require that a variance or waiver not be granted until the criteria can be met. The third criteria relates to the determination that the literal application of the rule to the facility will impose an undue burden upon the applicant. Again, since the rules are only minimum standards, there must be some indication as to the hardship that literal compliance with the rules will create. Without this criteria, a variance or waiver could be requested for only minor problems or in situations where the facility did not make an attempt to attain compliance with the rule. A license to operate a health care facility is premised upon the assumption that the licensee agrees to comply with the licensing laws. An obligation is imposed on the licensee to take all necessary steps to operate the facility in accordance with the applicable laws and rules of the state. Thus, in addition, every reasonable attempt should be made to comply with these minimum standards in order not to diminish the intent of the rules through the granting of variances and waivers for frivolous purposes. This criteria assures that a

variance or waiver will be granted only in those situations where literal compliance would be extremely difficult. The three criteria provide a reasonable method to evaluate the requests for a variance or waiver since the criteria assures that the Department's responsibility to protect patients and residents is not jeopardized and since the criteria support the general application of the licensing rules. Section b. states that the Department will notify the applicant in writing as to the Department's decision and requires that the notification specify the period of time that the variance or waiver will be effective and the alternative measures, if any, that will be taken by the applicant. This rule is necessary to assure that the applicant is fully apprised as to the Department's position and informed of the length of time that the variance or waiver will be granted and what alternative measures will be imposed.

Section 4 - Effect of Alternative Measures or Conditions.

This section specifies that the alternative measures or conditions imposed by the Department will have the force and effect of the licensure rules and will be subject to the issuance of correction orders and fines in accordance with the applicable laws. The rule also specifies that the period of time for correction and the amount of the fines will be governed by the rule for which the variance or waiver was requested. This section provides the Department with a mechanism to assure that a facility complies with any alternative measures or conditions. Without this section, there would be no way to enforce the alternative measures since they would not be considered duly promulgated rules. Since the Department's decision granting a variance or waiver will usually be based upon the fact that alternative measures or conditions will be met, it is important to provide a means to enforce these measures. Since the statutes re-

lating to the issuance of assessments require that fines be assessed in accordance with a promulgated schedule of fines, the last sentence of this section is necessary to assure that assessments could be issued in the event the facility fails to comply with a correction order. That sentence indicates that the fines, and for nursing homes, the specified period of time for correction, will be in accordance with the rule for which the variance or waiver is granted.

Section 5 - Renewal

This section is necessary to assure that a mechanism is established to process any requests for the renewal of a variance or waiver. In most cases, the variance or waiver will be time-limited and if the conditions giving rise to the original request have not changed, it might be necessary for the facility to renew the variance or waiver. Section a. states that the information contained in the renewal request be in accordance with the provisions of section 2. The same information will be needed to appropriately evaluate the renewal request. Section b. states that the renewal shall be granted if the criteria in section 3. continues to be met. This is reasonable since the renewal should only be granted upon the Department's determination that the health, treatment, safety, comfort and well-being of patients and residents will continue to be protected. In addition, prior to the approval of any renewal, the applicant will also have to demonstrate compliance with the alternative measure or conditions imposed at the time the original variance or waiver was granted. This is a reasonable requirement since the original variance or waiver was premised upon the substitution of these alternative measures or conditions and the applicant should demonstrate that compliance was attained.

Section 6 - Denial, Revocation or Refusal to Renew

This section states that the Department shall deny, revoke or refuse to renew a variance or waiver if the criteria in section 3. are not met. The rule specifies that the applicant will be notified of the decision and informed of the right to appeal.

Section 7 - Appeal Procedure

This section specifies that any appeal will be conducted as a contested case under the provisions of the Administrative Procedures Act, Minnesota Statutes, § 15.0411 et. seq. The rule requires that the appeal be requested within 15 days of the receipt of the Department's decision. This is reasonable in order to assure that the decision of the Department is appealed in a timely manner. This section also requires that the request for the hearing set forth in detail the reasons why the applicant contends that the decision of the Department should be reversed or modified. This is necessary in order to clarify the specific grounds for the appeal and is reasonable since in many situations the applicant may only be challenging a portion of the Department's decision. This will clearly establish the grounds for the appeal and possibly could result in an informal disposition of the appeal. The rule also specifies that the applicant will have the burden of proving that the criteria in section 3 have been met. This is a reasonable requirement since the applicant should be in the position of demonstrating that the criteria have been met and that the Department erred in not granting the variance or waiver.

7 MCAR § 1.046 L. Use of Oxygen

I General

The 1972 rule, which prohibited the administration of oxygen on an other than emergency basis was directed at preventing nursing homes from admitting and retaining acute care patients in a long term care setting. At the time of the promulgation of that rule, the extent of placement problems for persons requiring oxygen on a long term basis was an unknown factor. The medical condition of the type of resident admitted to a nursing home has changed since 1972, and oxygen usage within the nursing home setting is a growing occurrence. At least fifty nursing homes have received approval from the Department to care for persons requiring oxygen therapy for chronic diseases. Chronically ill patients, formerly considered "acute-care" only, are now being placed in nursing homes with regularity. Advances in technology have made oxygen therapy safer and more commonly accepted. These facts, along with the increasing difficulty in locating appropriate health facilities for persons requiring oxygen or oxygen therapy on a long term care basis has resulted in the determination to modify the requirements of that rule. Those modifications, which were part of the nursing home rule revision, are in accordance with the LCRAP's recommendation to review the use of oxygen in light of current technology, the medical needs of nursing home residents and other relevant matters.

II Specific Analysis of the Rule

7 MCAR § 1.046 L.1.

This section of the rule is revised to remove the language which limited oxygen usage to emergency situations only. Since this section would allow the use of oxygen on an emergency basis, the language requiring a physician's order for oxygen is deleted since there would normally not be time to contact the physician

in a true emergency. The remaining language of the section is the same as the existing.

7 MCAR § 1.046 L.2.

The new language allows oxygen to be administered in a nursing home on other than an emergency basis. The rule specifies that the nursing home has the option of admitting and retaining patients needing oxygen. L.2. applies only to those nursing homes admitting patients needing oxygen and establishes the requirements which must be met. The requirements are necessary to protect the health and safety of the patients and to assure that oxygen, which is considered a medical treatment, is properly administered.

7 MCAR § 1.046 L.2.a.

This rule requires that there be 24-hour licensed nurse coverage, unless admission to the nursing home is limited to persons who self-administer oxygen by physician order. Before a patient is allowed to self-administer oxygen a physician must certify that the patient is capable of administering and knows and carries out the proper procedures without nursing staff support.

For patients receiving oxygen other than on a self-administered basis, 24-hour licensed nurse coverage is necessary to assure that a qualified individual is available at all times. The administration of oxygen is a nursing function that is to be performed only by licensed staff who are knowledgeable of the procedures. Facilities which are federally certified as skilled nursing facilities (SNF) are currently required to provide 24-hour licensed nurse coverage under existing rule. Since it is likely that SNF's would be the type of facility most interested in and able to admit patients needing oxygen, the 24-hour licensed nurse coverage requirement is not an increase in requirement under existing rules. Currently 71% of the state's nursing homes are certified SNF, thus this rule may not place any additional staffing demands on any nursing home.

7 MCAR § 1.046 L.2.b.

A written order by a physician for oxygen is required because oxygen is a medical treatment which could be considered dangerous or harmful if improperly administered. An existing rule requires a physician's order for medical treatment (MHD 49 (c)(1)). The language of L.2.b. is necessary to assure that the need for oxygen is to be considered part of the patient's medical plan of care. As with other physician's orders, the oxygen order must be in the patient's chart so that staff can be informed of any special requirements.

The determination of a patient's capability to self-administer oxygen is based upon the physician's judgement. He or she has the responsibility for the medical care of the resident and must decide if the patient is mentally capable of understanding and physically capable of carrying out the proper procedures for self-administering oxygen. Since L.2.a. does not require 24-hour licensed nurse coverage if only self-administering patients are admitted, the physician's documentation that a patient is capable of self-administration is necessary in determining the need for licensed coverage. Moreover, the requirement of a physician's order for oxygen is reasonable for the protection of the patient.

7 MCAR § 1.046 L.2.c.

Under MHD 45(h)(7), nursing homes are required to have a multi-disciplinary patient care policy committee to develop and implement guidelines for care. Since the provision of oxygen is an aspect of patient care, it is appropriate and reasonable to require this group to develop policies relating to the administration of oxygen. These policies are necessary to provide guidelines for proper administration of oxygen. The multi-disciplinary nature of the Patient Care Policy Committee will assure that the limitations and restrictions necessary for safe administration of oxygen are considered. The minimum required elements are necessary to assure that

the health and safety of all patients will be fully protected.

7 MCAR § 1.046 L.2.c.(1)

The nursing home's policies for oxygen use should address any limitations to be placed upon each patient for the protection of the patient such as room assignments and smoking. The individual's rights along with the privacy rights of other patients are issues to be considered. The establishment of this policy provides for uniformity and notification to patients as to what the facility expects of them.

7 MCAR § 1.046 L.2.c.(2)

Policies which place restrictions on patients using portable oxygen are necessary for the safety of all patients to assure that the oxygen usage does not constitute a fire hazard. Patients must be informed of the activities from which they are restricted and a uniform policy should be established to reasonably protect the individual rights of the patient.

7 MCAR § 1.046 L.2.c.(3)

Because the physical and mental capabilities of a patient may change, the nursing home's policy should require periodic evaluation of each patient's ability to continue to self-administer oxygen. If self-administration is no longer possible and the facility administers oxygen, it must meet the requirement for 24-hour licensed nurse coverage or arrange for transfer of the patient. It is reasonable to require the facility to periodically assess the capabilities of patients to self-administer oxygen since the nursing home has the responsibility for the daily care of the patients.

7 MCAR § 1.046 L.2.(c)(4)

Additional precautions beyond the basic safety requirements in section 1.a-d may be necessary for individual nursing homes depending on the environment, level of staff capability, size of the facility and number of patients using oxygen.

7 MCAR § 1.046 L.2.d.

A patient has the right to be notified as to what is expected by the nursing home. Limitations and restrictions are developed by the facility for the health and safety of the patients and the patients should be made aware of these policies. Since policies in these areas are required to be developed, this section will not create an additional burden for the facility.

7 MCAR § 1.046 L.2.e.

Staff orientation and training are required under the provisions of MHD 45(h)(2)(ee) and MDH 50(d). The director of nursing services is responsible for orientation and inservice education as required by MHD 50(f)(3). The same rule specifies that nursing personnel shall be assigned duties consistent with their training, and MHD 45(h)(2)(ee) requires orientation and in-service to assure that employees understand the proper method of carrying out all procedures.

Since facilities will be permitted to either administer oxygen or admit self-administering patients, the rule is necessary to assure that training in these areas be provided at least as part of orientation and in-service education programs. Personnel should be familiar with the procedures relating to oxygen administration and the monitoring of self-administering patients in addition to necessary precautions and care of equipment.

7 MCAR § 1.046 L.2.f.

The development and implementation of policies and procedures for care of equipment and supplies are necessary to assure for proper handling and to prevent fire and other hazards. Proper care of equipment and supplies assures that they are clean and sanitized for patient use. Staff must have policies and procedures to properly store, clean sanitize and care for equipment and supplies.

7 MCAR § 1.047 & 7 MCAR § 1.049 Tuberculosis Screening

General

The purpose of screening for pulmonary tuberculosis in institutions is to prevent transmission of tuberculosis infection. Through screening, infected persons are identified so they can receive treatment to prevent the development of disease, and persons with the disease are detected so they can be treated. (1)

In 1973, in the U.S., there were an estimated 15 million positive tuberculin skin test reactions affecting 7 percent of the population. Most of the infected persons are over 35 years of age. Relatively few new infections are now occurring. The average number of new infections per year in areas such as Minnesota that have little tuberculosis disease is estimated to be 1 person per 10,000 population. Despite the low risk of infection to the general population, using epidemiologic data it is possible to define groups in which there is a higher risk of tuberculosis.

In Minnesota in 1978, 175 cases of tuberculosis occurred. Analysis of the cases by age reveals that 5 cases occurred in children under 5; 1 case was found in 5-14 year olds; 14 in 15-24 year olds; 39 in 25-44 year olds; 42 in 45-64 year olds; and 74 cases were diagnosed in persons 65 and older. 88.6% of the cases occurred in persons over the age of 25. 42.3% of these were in individuals age 65 and over.

The very low incidence of tuberculosis in Minnesota makes routine screening of the population unnecessary. However, screening of nursing home residents and staff is still recommended by the Minnesota Department of Health's Tuberculosis Screening Unit in the Chronic Disease Control Section of the Disease Prevention and Control Divison.

The proposed rules are based upon the joint recommendations of the American Thoracic Society which is the medical section of the American Lung Association, and the Center for Disease Control.

7 MCAR § 1.047 and 7 MCAR § 1.049 are discussed together because the issues concerning tuberculosis screening for employees and patients or residents are similar. Many of the terms are the same for both rules and to avoid repetition, explanations are stated only once. Although both rules are designed to assure that nursing home patients and residents are protected from tuberculosis transmission, the differences in the risks for staff and residents dictate the different requirements. In addition, the attached references contain support for both rules.

Analysis of Rule

7 MCAR § 1.047 Personnel.

A. Tuberculosis testing of employees.

Employees are given a tuberculin skin test prior to employment to determine if they are infected with tuberculosis bacteria. The responsibility for testing is placed upon the facility since it is accountable for the health, treatment, comfort, safety and well-being of the patients and residents. The employment of staff free from tuberculosis is a part of that accountability. The rule is necessary so that the facility protects other staff as well as residents from the disease. Because the facility is responsible for assuring the testing, it is reasonable to require the nursing home to provide the testing or to reimburse its employees for the costs of obtaining the tests.

A.1. The requirement to use the standard intradermal tuberculin test with purified protein derivative (PPD) (Mantoux) coincides with the American Thoracic Society's recommendation that this be the test of choice when sensitivity and specifity are

required, as is the case when the nursing home population's high risk is considered. Published studies correlating use of intradermal PPD with the other available methods have demonstrated a higher incidence of false positive reactions and some false negative reactions occurring with the multipuncture tests (not intradermal PPD). (2)

Individuals may be known to be positive reactors through previous testing or because they have undergone preventive therapy which, although preventing the disease, does not eliminate the presence of infection, therefore resulting in all subsequent skin tests being positive. When a positive reaction is verified by a physician, the employee is exempt from the skin testing but must comply with the requirements of A.1.b. or A.2. as appropriate.

A period longer than forty-five days prior to employment would identify most of the employees with tuberculosis infections and disease, but could result in failing to identify those individuals at highest risk of developing tuberculosis disease since newly infected persons are the group most likely to develop the disease. (3)

A period shorter than 45 days may present undue hardship for the employee since not only the skin test must be applied and read 48 to 72 hours later, but in the case of a positive skin test, the employee must also submit a chest x-ray within 45 days prior to employment.

A.1.a. Annual tuberculosis screening of all employees is no longer necessary due to the low incidence of tuberculosis in Minnesota and the low risk of acquiring new infections. Therefore, if new employees are tuberculin skin tested to see if they are already infected and are found to be not infected, no additional routine testing will be required. (1)

A.1.b. Positive skin tests are interpreted to mean the employees are infected: that is, they have tuberculosis bacteria living in their bodies. Persons who are infected with the tuberculosis bacteria may go on to develop tuberculosis disease that can

spread to others. Those persons who have recently become infected are at high risk of developing tuberculosis disease since the risk of the tuberculosis infection progessing to disease is greatest in the first five years after the infection has been acquired. For this reason, chest x-rays are required of employees for only the first five years after a positive skin test. Infected employees who have remained well the first five years after becoming infected have a low risk of subsequently developing disease, and thus, present a low risk to patients and residents. Routine periodic x-rays of persons who are no longer at high risk of developing tuberculosis disease is no longer recommended by the American Thoracic Society. It should be noted that, although the American Thoracic Society recommends that preventive therapy be considered for individuals with a normal chest x-ray, positive tuberculin test, and additional risk factors, the Department of Health cannot require such therapy. The generally low incidence of tuberculosis, however, is felt to reasonably warrant the acceptance of the five-year annual chest x-ray requirement for the purpose of protecting patients and residents.

Where required, all chest x-rays must be full-size, indicating that a complete view of the lungs is necessary. A 45-day time limit is placed upon the submission of the chest x-ray to give adequate time for the testing and to assure that tests are current reflections of the individual's health status.

A.2. The American Thoracic Society recommends preventive therapy for positive skin test reactors in order to diminish the risk of developing the disease, especially if the individual is young. It then excludes persons receiving preventive therapy from additional evaluation. (3) Therefore, individuals who have completed a program of preventive therapy are considered free from the disease and would not be required to submit to further testing.

A.3. It is necessary to require that documentation be filed in the employees' per-

sonnel record in order to assure that the screening requirements have been met and that employees are free from tuberculosis. MHD 48a(11)(cc) also requires the filing of dates and results of pre-employment and subsequent physical examinations of which the tuberculosis testing may be part.

The rule is necessary based on the continuing need to screen for tuberculosis disease in groups in which there is a higher risk of tuberculosis or in which even a sporadic case would present a significant hazard such as in the nursing home setting. The rule is reasonable in its provisions which are currently accepted practices in an organized screening program. The majority of individuals, after initial negative results, are exempt from further testing, while follow-up chest x-rays are required for only five years. Thus, testing and follow-up are focused on the higher risk persons and are required only until such risk is minimized for the protection of both employees and residents. The rule also provides for those persons who have had preventive therapy.

7 MCAR § 1.049 Physicians' Examinations and Orders

C.1. MHD 44(1) prohibits the admission of patients or residents who have or are suspected of having a disease endangering other patients or residents. Therefore, documentation of freedom from tuberculosis should be received prior to admission to assure that persons with the disease do not enter the nursing home and expose other patients or residents and staff to tuberculosis.

The chest x-ray is used for the initial test instead of the tuberculin skin test upon the recommendation of the Center for Disease Control and the American Thoracic Society. The body's immunity processes break down over time, resulting in an older person's inability to respond accurately to a tuberculin skin test as sensitivity to the tuberculin is reduced.

It is reasonable to require that the chest x-ray be taken within 45 days prior to admission in order to assure that the x-ray reflects the current status of the patient's or resident's health.

It is necessary to require documentation of freedom from active disease in order to assure the protection of other patients and residents. Individuals who have undergone preventive therapy are excluded from screening.

Because tuberculosis is more prevalent among nursing home residents than among the general population, every precaution must be taken to prevent the introduction of tuberculosis into a facility. The Department's requirement of a chest x-ray upon admission is a reasonable precaution.

References

(1) American Thoracic Society: Screening for Pulmonary Tuberculosis in Institutions. Am Rev Respir Dis 115: 901-906, 1977.

(2) Donaldson, John C. and Elliott, Robert C.: "A Study of Co.-positivity of Three Multipuncture Techniques with Intradermal PPD Tuberculin. Am. Rev Respir Dis 117: 843-846, 1978.

(3) American Thoracic Society: Preventive Therapy of Tuberculosis Infection. Am Rev Respir Dis 104: 769-775, 1971.

7 MCAR § 1.048 Records and Reports

General

There are two specific revisions in the existing rule. One relates to the time period required for retention of records and the other relates to the handling of patients' and residents' funds.

7 MCAR § 1.048 A.4. Storage and Preservation of Records

In discussions before the LCRAR, it was felt that the existing 10 year requirement for retention of resident records is unnecessary and burdensome. The lack of storage space in many facilities was one of the problems cited. Also, the federal regulations for skilled nursing facilities require that such records be retained in accordance with the controlling state statute, the state's statute of limitations, or, in the absence of a state statute, for five years from the date of discharge.

The Department believes that a five year retention period would be the appropriate minimum and would preserve records for an adequate period of time. In addition, since Minnesota does not have a specific state statute regarding retention of nursing home records, a five year minimum maintains uniformity with the above mentioned federal regulations.

A.8. Record of Patients' and Residents' Funds.

General

Issues were raised before the LCRAR concerning alleged violations of the existing rule and of MHD 46(f) which requires that no home handle resident affairs without the proper legal authorization. The concerns range from alleged commingling of funds, to requesting more stringent inspection and enforcement procedures to prohibiting facilities from handling resident funds entirely.

Aware of these concerns, the Department had developed a rule which was reviewed by the Nursing Home Advisory Council. The proposed rule is based upon the Nursing Home Advisory Council draft.

The rule is based upon the Department's statutory authority to protect the comfort and mental, as well as physical, well-being of patients and residents. The Department of Public Welfare (DPW) also monitors trust accounts of nursing home residents, but only for Medicaid recipients. The Department of Health, however, has a broad authority which applies to all nursing home and boarding care home residents. The Department reviewed the proposed rule with staff at DPW and included input from them (Exhibit F). The rule also protects the facility by establishing uniform standards in greater detail in order to clarify what is expected of the facility if personal funds are retained for safekeeping.

7 MCAR § 1.048 A.8.a.

The Department recognizes the concerns of nursing homes and boarding care homes regarding handling of funds. This section, requires the facility to develop a policy specifying whether or not it will handle funds. If the facility handles funds, these

rules shall be followed as part of the facility's policies.

A.8.b.(1)

Authorization is necessary to assure that consent has been given for the home to handle and protect funds. Authorization may be received only from the patient or resident or his/her legal representative. It is a right of the patient or resident to provide authorization and it cannot be delegated by others without the legal authority to do so.

(2) It is necessary to have written authorization retained in the record in order to demonstrate that there is consent from the proper person(s). These rules are reasonable because they also serve to protect the facility by assuring that there is written documentation evidencing the patient's or resident's consent to allow the facility to handle funds.

7 MCAR § 1.048 A.8.c.

This section requires the proper handling of the account to protect the interests of patients and residents. It assures that access to records is provided and that there be a quarterly accounting in accordance with M.S. § 144.651 (12). Record-keeping requirements are detailed and the right to access to funds is specified. There are also requirements for bank deposits and the prorating of any accrued interest.

7 MCAR § 1.048 c.(1)-(3)

There rules are necessary to assure that personal funds are completely separate in all respects from those of the nursing home or boarding care home. This separation is necessary to guard against use of the personal funds for the purpose of the facility and to protect the interests of the patients and residents.

In the case of residents in county homes, personal funds of patients or residents are required to be deposited with the county treasurer. (Minn. Stat. § 376.58, subd. 7 (1978). Other facilities are permitted to commingle patients' and residents' funds from within one facility.

Organizations which operate more than one facility are prohibited from commingling funds from all residents in order to assure that there will be clear identity of funds from each nursing home for accounting purposes and to provide for accessibility to these funds.

These are reasonable steps for the protection of residents' funds. The rule assures that accounts are established in such a way to clearly identify the funds belonging to the patients or residents of a particular facility and that these funds are not used for the purposes of the facility.

7 MCAR § 1.048 A.8.c.(4)

This rule establishes the minimum components for a record keeping system, which is necessary to assure that there will be proper accounting to the patients and residents.

Section (4)(a) requires that patients and residents be provided access to their financial records. Although the Department realizes that requiring access at any time would be burdensome, at least one hour per day 5 days per week is a reasonable minimum. Responsibility for establishing policy is placed upon the facility which is in the best position to establish reasonable times for access.

Section (4)(b) requires the provision of a written quarterly accounting which is also required by the provisions contained in the state and federal bill of rights.

Minn. Stat. § 144.651(12) requires that a quarterly accounting be provided and reference to this requirement in the rule is necessary to assure that this requirement is considered as part of the facility's responsibility for properly handling the personal fund accounts. The rule does allow the resident or patient to designate another individual to receive the quarterly statements.

In order to assure for uniform and appropriately complete accounting, section (4)(c) specifies the basic elements of the written record maintained for each patient or resident. The record of incoming funds should specify the date, amount and source of the funds to assure that the record fully reflects the amount of money deposited by or on behalf of the residents. The requirement that the source of the funds be identified provides a way to audit the records since funds could be received from many sources, e.g. friends, relatives, social security etc. The issue of who can withdraw funds, other than the patient or resident, is important and was discussed quite extensively by the Nursing Home Advisory Council. Concerns were expressed that individuals would withdraw funds from the accounts without the permission of the patient or resident. To avoid these situations, the rule requires that the record specifically indicates the individuals who have the right to withdraw funds from these accounts. The date and amount of withdrawals are information necessary to assure for complete accounting of funds. In order to assure that the funds are used for the purpose of the patient or resident, this rule requires that purchase receipts be placed in the record if money is withdrawn by persons other than the patient or resident. This will assure that the money will be used for the welfare of the patient or resident. This portion of the rule is similar to the requirements contained in Minnesota Statutes § 256B.35 subd.4, which requires that the personal allowance of Medicaid recipients be transferred only when the money will be used for the benefit of the patient or resident.

7 MCAR § 1.048A.8.c.(5)

This rule is necessary to assure for safety of funds. One hundred dollars is a reasonable limit since it allows the facility to maintain a considerable amount of cash on hand. It is important that the facility have only a fiduciary interest in the funds to assure that they are not being used for the purposes of the home. Records of deposit and withdrawal are maintained as an accounting requirement to indicate the amount of the funds belonging to individual residents.

7 MCAR § 1.048 A.8.c.(6)

The rule is necessary to protect the money belonging to the resident. Interest accrued cannot be used by the facility for any purpose. If interest-bearing accounts are maintained, the interest must be prorated to reflect interest earned on individual accounts if separate accounts for each resident are not maintained.

7 MCAR § A.8.c.(7)

The facility policy should specify the period each day that residents may request withdrawals. As with records access, the Department realizes that access at any time would be burdensome and, therefore, the facility is given responsibility for specifying periods of access. It is reasonable to require funds from outside the facility be returned within three banking days due to weekend closings and the paperwork procedures that are necessary. A policy allowing access is also necessary to assure that patients or residents who are reluctant to keep funds in their room can easily withdraw their funds from the facility account.

7 MCAR § 1.048 A.8.d. and e.

These rules are necessary to assure that there is access to funds under these circumstances. For the purpose of this rule, patients and residents whose beds are

held for their anticipated return are not considered discharged. The accounting is necessary to assure for the accurate handling of the funds and will also provide protection to the facility when the account is closed for a particular patient or resident.

7 MCAR § 1.048 A.8.f.

Written verification by a public accountant assures that the personal funds of the patients and residents continue to be maintained and protected before and during change of ownership proceedings. This protects the patients and residents and both the old and new owners. The use of a public accountant provides for objectivity and accuracy in determining the exact status of the accounts.

7 MCAR § 1.052A.1 Double Bed Usage

I General

The LCRAR recommended suspension of the existing MHD 52(a)(1) which prohibits the use of double beds. The Department decided to repeal the language of the rule which prohibits double bed usage and add language requiring the development of a policy regarding the use of double beds.

II Specific Analysis of the Rule

The Department maintains its concern for the provision of bedside care and the privacy of the residents involved. It is felt that the use of double beds should be a facility decision based upon the nursing needs of the patients and residents, privacy and space considerations, and the anticipated effects on the patient's and resident's emotional and physical well-being. These can best be addressed through each facility's individualized policy.

7 MCAR § 1.053 Disposition of Medication

I General

The LCRAR recommended review of the existing rule in light of the changes in the Board of Pharmacy rules which permit the return of drugs dispensed under the "unit dose" system.

The Department promulgated the existing rule on advice and counsel of the Minnesota Board of Pharmacy which determined that destruction was the only safe method that should be permitted. Subsequent to that date, new Board of Pharmacy rules have been promulgated. See 7 MCAR § 8.032. Returns, under the Department's revised rule, will be governed by the provisions of the rules of the Minnesota Board of Pharmacy. The revised rule is reasonable because it provides an option regarding the disposition of medications.

II Specific Analysis of the Rule

7MCAR § 1.053 F.1.

The existing rule is changed to conform to the Board of Pharmacy rule. Forms will be obtainable from the Board of Pharmacy. New language is added to clarify that the return of drugs is an option.

7 MCAR § 1.053 F.2.

The newly added section references the procedures of the Minnesota Board of Pharmacy which establish controls for the return of drugs. It is reasonable to conform to the Board's rule because of its expertise and jurisdiction in this area.

7 MCAR § 1.055 U. Dishwashing

I. General

The use of chemical sanitizing has increased throughout the country as a result of changes in technology which make it more effective and because of widespread concerns regarding energy consumption and costs. Providers, along with various chemical suppliers, have expressed much interest in the introduction of low temperature-chemical sanitizing warewashing to nursing and boarding care homes. In March, 1979, a formal petition for rule-making was submitted by Economics Laboratory, Inc. regarding the use of this type of dishwashing machine. The petition for rule-making and the supporting materials submitted by Economics Laboratory, Inc. are attached as Exhibit H.

The times and temperatures established in the existing rule were based upon provisions contained in the Food Service Sanitation Manual of the U.S. Department of Health, Education and Welfare. At the time of the development of the 1972 rules, the Department felt that the utilization of a dishwashing method requiring exposure to hot water would best assure the control of disease-causing organisms. The Department has expressed concern in the past regarding potential problems with chemical sanitizing. Since the existing rules were promulgated, however, changes in technology have occurred and information has been submitted from a number of sources regarding low temperature dishwashing. The 1976 revised Food Service Manual published by FDA provides for the use of chemical dishwashers. The revised rule is based upon the FDA's recommendations.

II. Specific Analysis of the Rule

7 MCAR § 1.055 U.1.a.

The language of the existing rule is revised to delete the prohibition on chemical

disinfection.

7 MCAR § 1.055 U.1.b.(1)(a)

The quality of the equipment must be considered in order to assure that it is capable of performing its functions. The National Sanitation Foundation (NSF) has adopted specific standards for dishwashers based upon industry standards. Machines are approved by NSF upon determination that the machine complies with its adopted standards. The rule ties into NSF approval by requiring all machines to bear labeling which signifies NSF approval.

Approved dishwashing machines are necessary to assure that proper equipment is used so that, in turn, dishes and utensils will be properly cleaned and sanitized.

7 MCAR § 1.055 U.1.b.(1)(b)

Since machines rely upon chemicals for sanitization, it is necessary to provide assurance that chemicals are being introduced into the rinse cycle so that proper sanitization will take place. An audible signaling device helps to reduce human error which might occur. Literature available to the Department indicates that machines are usually equipped with such a device. A signaling device was also part of the proposed rule suggested by Economics Laboratory, Inc.

In order to remain effective and perform its function, it is necessary to maintain the device in an operating condition.

7 MCAR § 1.055 U.1.b.(1)(c)

This rule is found in the 1976 revised Food Service Manual published by FDA. At a pressure of less than 15 pounds per square inch there is not enough water through the jets to assure thorough rinsing. Above 25 pounds per square inch

the water will atomize into a vapor and preclude rinsing. A pressure gauge is necessary to provide a device for monitoring proper pressure for effective rinsing.

7 MCAR § 1.055 U.1.b.(1)(d)

Counter space is necessary to assure proper air drying to prevent contamination. The required space is reasonable because it is sufficient to allow drying. The rule does not prohibit vertical storage of racks on a shelf if horizontal space is limited. Air drying is of particular concern with the low temperature/chemical sanitizing dishwashing machine since the dishes are subjected to lower temperatures and take longer to dry. For that reason, it is important to assure that there is sufficient space to allow for the air-drying of dishes and utensils.

7 MCAR § 1.055 U.1.b.(2)

The rule is designed to assure that the machine will be properly used, which will, then, assure that dishes and utensils are sanitized to prevent any possibility of contamination.

7 MCAR § 1.055 U.1.b.(2)(a)

To assure proper operation, the dishwashing machine should be operated according to the instructions recommended by the manufacturer. Posting of the instructions is reasonable because it assists the facility in continued proper operation and provides the surveyor with an easy reference for monitoring compliance. Operating the machine in accordance with the manufacturer's recommendations assures that the dishes and utensils are subjected to the proper washing, rinsing and sanitizing cycles.

7 MCAR § 1.055 U.1.b.(2)(b)

This rule differs from the FDA's recommendation that the temperature of wash water shall not be less than 120°F. The Department believes that the proposed higher minimum temperature provides for a more thorough cleaning process, which is important to promote effective sanitization. Higher heat exposure will also reduce the drying time of the dishes and utensils.

A 140°F. minimum temperature for the wash water was also suggested in the proposed rule submitted along with the rule-making petition from Economics Laboratories, Inc.

7 MCAR § 1.055 U.1.b.(2)(c)

In order to eliminate human error and assure proper flow of chemicals, it is necessary to require automatic dispensing of chemicals.

Time and concentration are important variables in effective sanitization. Dispensing of chemicals in accordance with the manufacturer's specifications is necessary to provide proper sanitization and to prevent the possibility of toxic residue resulting if concentrations are too high.

7 MCAR § 1.055 U.1.b.(2)(d)

The rule is consistent with FDA recommendations. A minimum temperature is necessary to assure that proper sanitization occurs. Chemical sanitizers increase in activity at temperatures above 75°F. resulting in enhanced germicidal action and the most effective sanitization. Individual machine manufacturers may specify another temperature for most effective sanitization and this recommendation should

be followed in order to properly operate the machine.

7 MCAR § 1.055 U.1.b.(2)(e)

All chemicals which make a claim that they provide bactericidal benefits must be registered by the EPA. EPA analyzes the product to determine that use of the product is safe and that claims of the bacteria-killing effect are valid. The product will carry a label containing the EPA registration number and specific instructions for use. The registered label provides an easy method to verify that the product used in the machine is safe. Proper sanitizing is assured through following the instructions for use found on the label.

The FDA has established a standard concerning the types of chemical sanitizing solutions that can be used in food service establishments (21CFR 178.1010). No specific product approval is made by FDA.

7 MCAR § 1.055 U.1.b.(2)(f)

Since proper sanitization is accomplished through the use of chemicals, it is necessary to assure that the proper concentrations are used for each washing process. The rule provides a reasonable method for accomplishing this.

7 MCAR § 1.055 (2)(f)(i)

Testing is necessary at each machine use in order to protect the patients and staff from improper operation. The most effective testing procedure would be recommended by the manufacturer's instructions.

7 MCAR § 1.055 (2)(f)(ii)

A written log will provide the facility with a history of its dishwasher's opera-

tion and reliability. It also serves as a check on the required testing and is an easy reference for surveyors to monitor compliance. A three month record is reasonable for these purposes.

7 MCAR § 1.055 U.1.b.(2)(g)

This rule is also part of the section on hot water washing. It is repeated because this section deals specifically with chemical dishwashing. Washing of hands between handling of soiled and clean dishes prevents contamination and represents a reasonable safeguard that can be taken.

7 MCAR § 1.055 U.1.b.(2)(h)

This rule is also found in hot water washing. Air drying reduces the handling of dishes and utensils, which will minimize the chances for contamination.

7 MCAR § 1.055 U.1.b.(2)(i)

Thorough daily cleaning is necessary to assure continued proper operation. Cleaning will be most effective when the manufacturer's recommendations are followed.

7 MCAR § 1.057 Schedule of Fines for Uncorrected Deficiencies.

I General

This rule establishes the amount of a fine that will be assessed to a nursing home or a boarding care home for non-compliance with correction orders. Section A. and Section B. are existing rules while Section C. is a new schedule of fines that is based on the rules presented at the April 1, 1980 public hearing. The only change made in Section A. is the re-numbering to be in accordance with the requirements for the Minnesota Code of Agency Rules. Section B, in addition to being re-numbered, contains the appropriate reference to the provisions of Section C. The statutory authority for promulgating Section C. is contained in Minnesota Statutes § 144A.10 subd. 6 (1978) which provides that: "a nursing home. . . shall be assessed a civil fine in accordance with a schedule of fines promulgated by rule of the Commissioner of Health. A 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. . . ." Thus, it should be noted that the provisions of Section C. will, first, apply only to facilities licensed as a nursing home and, second, will provide for the daily accrual of fines in accordance with the provisions of Minn. Stat. § 144A.10 subd. 6 and subd. 7. (1978) It should also be emphasized that the new schedule of fines will only apply to the new rules and that the existing schedule of fines contained in Sections A. and B. will still be applicable to nursing homes and to boarding care homes in accordance with the provisions of Minn. Stat. § 144.653 and the continuity provisions of Minn. Stat. 144A.29 (1978). The provisions of Section C. will only apply to those rules specifically enumerated within that section.

The schedule of fines contained in Section C. provides for three levels of assessments in the amount of $50, $150 and $250. The Department has the authority to assess fines up to $250 per day (Minn. Stat. 144A.10, subd. 6.) While it

would be possible to develop a greater number of fine levels, the Department feels that the establishment of three levels provides a workable and equitable mechanism. The three levels were based on the degree of harm that would result if the nursing home fails to comply with the provisions of the rule. A $50 penalty assessment will be issued for a violation of these rules which have only a minimal relationship to the health, safety, treatment, comfort or well-being of a patient in the nursing home. A violation of these rules would not create a situation which would jeopardize the health or safety of a patient. A $150 penalty assessment will be issued for a violation of those rules which could potentially create a situation jeopardizing the health, safety, treatment, comfort or well-being of the patient. A $250 penalty assessment will be issued for a violation of these rules which would create a situation jeopardizing the health, safety, treatment, comfort or well-being of the patients.

The Department believes that the three levels provide a rational basis for issuance of penalty assessments based on a degree of harm that a violation of the rule would present to the patients in a nursing home. It should be emphasized that the Department cannot issue a fine to a nursing home until after the issuance of a correction order and until the expiration of the specified period of time for correction has elasped. Thus, prior to being in a situation which would result in the issuance of a fine, the nursing home is fully informed as to the nature of the deficiencies and provided a period of time in which to make the necessary corrections. It is only in those situations where the facility has failed to comply with the correction order and upon reinspection the Department determines that the facility is still in non-compliance with the licensing rule that the fine will be assessed.

II Specific Analysis of the Rule

Section C.1.

This section contains those specific rules for which a $50 penalty assessment will be assessed on a daily basis to a nursing home for non-compliance with correction orders. As previously mentioned in regard to the $50 fining category, these 13 rules have only a minimal relationship to the health, safety, treatment, comfort or well-being of the residents, and the violation of one of these rules would not create a situation jeopardizing the health or safety of the patient. The rules that are contained in this $50 fining category are as follows:

a) 7 MCAR § 1.048A.4.

The failure of a nursing home to maintain records for a period of five years after the death or discharge of a patient would obviously have a minimal effect on the health, safety, treatment, comfort or well-being of the patients.

b) 7 MCAR § 1.048A.8.a.

The failure of the nursing home to develop the admission policies which specify whether the home will accept personal funds of a patient also would have a minimal relationship to the health, safety, treatment, comfort or well-being of the patients. While the provisions of the rule relating to the handling of funds would have an impact on the well-being of the patients in the facility, the fact that the policy is not developed has only a minimal effect on the patients' well-being. Thus, the $50 fine for a violation of this rule is appropriate.

c) 7 MCAR § 1.048A.8.b.(2).

The failure of the facility to retain the written authorization allowing the facility to handle a patient's funds would also have a minimal effect on the health, safety, treatment, comfort or well-being of the patient. While the failure to have a written authorization would have an impact on the patients' well-being, the failure of the facility to retain that authorization on file has only a minimal

relationship to the patient's well-being. Thus, violation of this rule justifies the imposition of only a $50 fine.

d) 7 MCAR § 1.048A.8.c.(3).

The violation of this rule, which would be based upon the fact that patient's funds from a number of facilities are combined in one account, containing patient funds from a number of facilities, would also only have a minimal relationship to the health, safety, treatment, comfort or well-being of the patients in a nursing home. Thus, the $50 fine for the violation of this rule is appropriate.

e) 7 MCAR § 1.048A.8.c.(5).

The failure of a facility to deposit the funds of a patient in excess of $100 in a financial institution would have minimal effect on the health, safety, treatment, comfort or well being of a patient in a nursing home. While the rule is to assure that these funds are maintained in a safe location, the mere failure to place funds in excess of $100 in a bank would not in itself have a jeopardizing effect on the patients. Thus, the Department feels that the $50 fine for a violation of this rule is appropriate.

f) 7 MCAR § 1.048A.8.c.(6).

The failure of the nursing home to pro-rate interest accruing to individual patients, would also have a minimal relationship to the health, safety, treatment, comfort or well-being of the patient. The rule was intended to assure that if interest is accrued in the accounts, that the interest is attributed to the proper patients. However, failure of the facility to comply with this rule would justify only the issuance of the $50 fine.

g) 7 MCAR § 1.048A.8.d.

The nursing home's failure to comply with the provisions of this rule would have only a minimal relationship to the health, safety, treatment, comfort or well-being of the patients in the facility. While the facility is, of course,

required to return the funds, the violation of this particular rule would only justify the issuance of the $50 fine.

h) 7 MCAR § 1.048A.8.e.

A violation of this rule would have only a minimal relationship to the health, safety, treatment, comfort or well-being of the patients in the facility. This rule requires that the funds of a patient be returned to the appropriate individuals after the death of the patient and the Department feels that the $50 assessment for a violation of this rule would be appropriate.

i) 7 MCAR § 1.048A.8.f.

The failure of a nursing home to comply with the provisions of this rule requiring an audit of the trust fund accounts would have a minimal relationship on the health, safety, treatment, comfort or well-being of the patient. For that reason, the Department feels that the $50 fine for a violation of this rule is appropriate.

j) 7 MCAR § 1.052A.1.b.

The failure of a nursing home to develop the policy regarding the use of double beds would also have a minimal relationship on the health, safety, treatment, comfort or well-being of the patients in the facility. The fact that the policy does or does not exist would not have direct impact on the care provided to the patients and for that reason, the Department feels that the $50 fine for a violation of this rule is appropriate.

k) 7 MCAR § 1.053F.2.

The facility's failure to comply with this rule, which authorizes the return of drugs in accordance with the Board of Pharmacy rules, would also have only a minimal relationship on the health, safety, treatment, comfort or well-being of the patients in the facility. The rule would not create a situation jeopardizing the health or safety of the resident through its noncompliance and, for that reason, the Department feels that the $50 fine is appropriate.

1) 7 MCAR § 1.055U.1.b(1)(d).

The failure of the facility to have space for at least four racks of clean dishes also would have only a minimal relationship to the health, safety, treatment, comfort or well-being of the patient in the facility. The primary purpose of this rule is to assure that adequate space for air drying is provided. Failure to provide such space is likely to have only a minimal relationship on the patient's health or safety. For that reason, the Department feels that the $50 fine is appropriate.

Section 2. $150 penalty assessments.

This section of the rule enumerates those particular rules for which a violation will subject the nursing home to a penalty assessment in the amount of $150 per day. The 25 rules contained in this section could potentially create a situation which would jeopardize the health, safety, treatment or well-being of the patient if the nursing home is in non-compliance with the provisions of the particular rules. The rules contained in this section are as follows:

a) 7 MCAR § 1.046L.2.b.

This rule requires that the attending physician submit orders for the use of oxygen and, in situations where self-administration is ordered, the physician shall also indicate that the patient is capable of self-administering oxygen. The failure to have written physician orders authorizing the use of oxygen could create a situation which would jeopardize the health or safety of the patient. Since oxygen is considered to be a medication, written orders should be obtained prior to the administration of oxygen since those orders outline the frequency and amount of oxygen to be supplied to the individual patient. Thus, the Department feels that the $150 assessment for a violation of this rule is appropriate.

b) 7 MCAR § 1.046L.2.c.

This rule requires that the Patient Care Policy Committee develop and implement

written policies regarding the use of oxygen in the facility. These policies are designed to assure that the necessary limitations are placed on patients using oxygen, that the facility establishes any pertinent restrictions on the self-administration of oxygen, that the facility periodically assess those patients self-administering oxygen, and that precautions are taken to provide for the safe use of oxygen. The failure to develop policies in accordance with this rule could create a situation that might jeopardize the health, safety, treatment, comfort or well-being of the patients. The policies are designed to assure that proper safeguards for the use or administration of oxygen and to assure that the policies are developed and implemented within the facility. Thus, the Department feels that the $150 penalty assessment for a violation of this rule is appropriate.

c) 7 MCAR § 1.046L.2.d

This rule requires that the facility inform those patients who require oxygen of any limitations or restrictions imposed by the nursing home. The limitations and restrictions developed by the facility are for the protection and safety of the patients and patients must be aware of these limitations and restrictions. Thus, the failure to comply with this rule could create a situation that would jeopardize the health, safety, treatment, comfort or well-being of the patient.

d) 7 MCAR § 1.046L.2.e.

This rule requires that the director of nursing be responsible for training the staff in the administration of oxygen. Staff training is critically important to assure that oxygen is administered properly and safely, that the patient's response to oxygen is carefully monitored, and that the equipment is properly cared for and cleaned. The failure to provide this training could create situations where un-trained personnel are involved in oxygen administration which could jeopardize the health, safety, treatment, comfort or well-being of the patient. Thus, the

Department feels that the $150 assessment for violation of this rule is appropriate.

e) 7 MCAR § 1.046L.2.f.

The failure of a nursing home to develop and implement policies regarding the care, storage, cleaning and sanitizing of oxygen tanks, equipment, and supplies could result in a situation which could jeopardize the health, safety, treatment, comfort or well-being of the patients. It is important to assure that the oxygen equipment is properly stored in order to prevent the creation of a fire hazard and it is also necessary to assure that the equipment is properly cleaned and sanitized to avoid the transmission of diseases to patients within the facility. Thus, the Department feels that the $150 fine for a violation of this rule is appropriate.

f) 7 MCAR § 1.047A.

The purpose of the rule requiring the tuberculosis testing of employees is to insure that its employees are free from tuberculosis prior to beginning employment within the facility. Due to the communicable nature of tuberculosis, the Department believes that the screening measures required by this rule are necessary to protect the health of the patients living in the nursing home. Failure to comply with the provisions contained in this rule could possibly create a situation by which patients in the facility could be exposed to an individual with an active case of tuberculosis. Because a violation of this rule could create a situation jeopardizing the health and safety of the patients living in the facility, the Department feels that a fine of $150 should be imposed for a violation of any of the provisions contained in this rule.

g) 7 MCAR § 1.048A.8.b.(1)

Patients living in a nursing home should be assured that precautions are taken to protect the funds they have given to the facility for safe keeping, Thus, in

order to protect the well-being of the patients, the Department has developed a rule to safeguard the handling of patients' personal funds.

Failure of the facility to adequately care for and handle these funds could create situations which jeopardize the comfort and well-being of the patients. An important element in safeguarding patient's funds is the obtaining of a written authorization from the patient or patient's guardian to enable the facility to handle the funds. Thus, the failure to obtain this authorization could create a situation which would jeopardize the comfort and well-being of the patient, and for that reason, the Department feels that the issuance of a $150 fine for the violation of this rule is reasonable.

h) 7 MCAR § 1.048A.8.c.(1).

This rule requires that patients' personal funds be retained in accounts separate from those of the facility. Failure of the facility to comply with this provision could either result in the mishandling of funds or at least create concern among patients that their funds are being mishandled. For that reason, the Department believes that non-compliance with this rule could create a situation which would jeopardize the comfort and well-being of the patients and, therefore, the $150 fine is considered reasonable.

i) 7 MCAR § 1.048A.8.c.(2).

For the reasons specified above, the Department feels that the facility should assure that the funds are not used for any purpose connected with the nursing home or for other individuals. A violation of this rule could create a situation where the patients feel that their funds are not being appropriately handled. Thus, since this situation could potentially jeopardize the comfort and well-being of a patient the $150 fine is appropriate.

j) 7 MCAR § 1.048A.8.c(4)(a).

This rule allows patient to have access to the financial records maintained by

the facility to verify that their personal funds are being handled in an appropriate manner. A failure of the facility to comply with the provisions of this rule could create a situation where a patient feels that funds are not being properly maintained. Thus, the Department feels that the issuance of a $150 fine for a violation of this rule is reasonable.

k) 7 MCAR § 1.048A.8.c(4)(b).

For reasons similar to those stated above, the Department feels that quarterly accounting is a means to eliminate patient's concerns about the handling of their funds. Thus, the failure to provide the quarterly accounting statements could potentially create a situation which would jeopardize the comfort and well-being of the patients and for that reason, the Department feels that the $150 fine is appropriate.

l) 7 MCAR § 1.048A.8.c(4)(c).

This section requires that the individual written records be maintained showing the transactions made by or on behalf of the patient. This recordkeeping requirement is important in order to assure that patient funds are properly maintained. The recordkeeping system provides the means by which the patient or someone on the patient's behalf can determine how the funds are being handled and these records would demonstrate whether the funds are being properly maintained. A failure to comply with the provisions of these rules could create situations in which a patient feels that the funds are not being properly handled and thus could potentially jeopardize the comfort or well-being of the patient. For that reason, the Department feels that the $150 assessment is appropriate.

m) 7 MCAR § 1.048A.8.c.(7).

This rule requires that a facility provide the patient or other authorized individual with funds upon request, or, if the funds are maintained outside the

facility, within three banking days. The right of a patient to have access to their funds within a reasonable time is a significant right to the patients in a nursing home. A facility should assure that the patients are able to have access to their personal funds. Because violations of this right could create situations which could be disruptive to the patient's comfort or well-being, the Department feels that the imposition of the $150 fine is appropriate.

n-y 7 MCAR § 1.055U.1.

These twelve sections deal with portions of the rule relating to the use of dishwashers that chemically sanitize dishes and utensils. The requirements contained in this rule assure that the dishes and utensils are subjected to a thorough washing and sanitizing procedure, to prevent the transmission of any diseases to the patients in nursing homes. The failure to comply with these rules could result in situations where dishes and utensils are not being subjected to the proper sanitizing procedures. If that occurs, there is a possibility that illnesses could be transmitted to the patients from the unclean utensils and thus a potential situation is created that could jeopardize the health, safety and comfort of the patients in the facility. Thus, for each of the provisions listed in this rule, the Department feels that the $150 penalty assessment is necessary.

Section n, o, and p of this rule relate to specify certain standards for the dishwashing machines. The failure of the facility to have machines which meet the requirements established by the National Sanitation Foundation could result in a situation where dishwashing machines are being used which are not capable of providing proper sanitization. Section o. and section p. relate to special characteristics of the machine. Section o. refers to the rule which requires that a signalling device be maintained on the machine and that the device be in operating

condition. Since chemicals are a principal means for sanitizing dishes, it is important that such a device be on the machine and kept in an operating condition to signal when chemicals are no longer being injected. The failure to have such a device could lead to situations in which the dishes are not subject to the chemical sanitizing agents. In a similar fashion, the requirement that the water pressure for the rinse water be maintained at a certain specified pressure is necessary to assure that the dishes are subjected to the appropriate rinsing techniques. Thus, violations of either one of these two requirements could result in improper rinsing and sanitizing of the dishes.

Sections q. through y. relate to those requirements specifying the procedures to be followed in operating the dishwashing machines. These procedures are important to assure that the machine is appropriately maintained and that the dishes are subjected to the entire dishwashing process. Failure to comply with the procedures outlined in the rule could potentially create situations in which dishes and utensils are not properly sanitized and thus cause the patients to be subjected to outbreaks of foodborne illnesses. Section q. relates to the rule specifying that the machine should be operated in accordance with the manufacturer's instructions and that the instructions should be posted nearby. It is necessary to demand that the machine be operated in accordance with the manufacturer's instructions to assure that the dishes are subjected to the proper washing and sanitizing cycles. Section r. relates to that rule which requires that the wash temperature be maintained at a certain minimum to assure that the dishes are properly washed prior to the sanitizing cycle. Violation of this rule could jeopardize the sanitizing process if the dishes are not properly washed. Sections s. and t. relate to the use of chemicals and the temperature of the rinse water. It is important to assure that the chemicals utilized in the machine are automatically dispensed and that the rinse water is maintained at the proper temperature. This is necessary to assure that the dishes

are subjected to the proper concentration of the chemical at the proper temperature and for the specified period of time. Failure to comply with those requirements would impede the sanitizing process. Section u. and v. also relate to the use of the chemicals. Section u. requires that only those chemicals that have been registered by the Environmental Protection Agency can be used and that there are specific instructions for use of the chemicals. Failure to use properly registered chemicals could expose patients to toxic substances and to assure for proper use of the chemicals, it is necessary to assure that instructions are provided. Section v. requires that the facility measure the concentration of the chemicals by the use of a test kit. Violation of this rule could either expose patients to a toxic residue if a concentration is too high or could result in improperly sanitized dishes and utensils if the concentration is too low. Sections w. through y. refer to procedures to be followed in the operation of the dishwashing machine and these procedures also assure that the dishes are maintained in a sanitary condition. The requirement that any person who handles both soiled and clean dishes wash hands between operations is also found in the existing nursing home rules and is necessary in order to avoid contamination by assuring that there would be separation of the clean and soiled functions. For similar reasons, it is necessary that the dishes be air dried since towel drying of the dishes can contaminate them after they are cleaned and sanitized. The last section requires that the dishwashing machine be thoroughly cleaned in accordance with the manufacturer's recommendations. This is important to assure the proper functioning of the machine.

These rules are intended to protect the patients in the facility by assuring the proper cleaning and sanitization of dishes and utensils. The failure to comply with these sections could potentially create a situation which would jeopardize the health and safety of the patients. Thus, the imposition of a $150 fine for a violation of any one of these sections is reasonable.

Section C.3.

The final section of the schedule of fines lists the three rules wich are subject to the maximum fine of $250. This section contains the rules for which the failure to comply with their provisions will create a situation of jeopardizing the health, safety, treatment, comfort or well-being of the patient and, thus, the imposition of the maximum fine is necessary. The rules that are subject to the imposition of the $250 fine are as follows:

a) 7 MCAR § 1.046L.2.a.

This rule requires that a nursing home which admits or retains patients requiring oxygen on other than a self-administered basis, provide 24-hour licensed nurse coverage. The requirement for the 24-hour licensed nurse coverage is to assure that trained nursing personnel are available at alltimes to properly and safely administer oxygen within the facility. The administration of oxygen is a nursing function and must be provided under the supervision of licensed personnel only. Thus, the failure of a facility to maintain licensed coverage on a 24-hour a day basis will jeopardize the health and safety of the patients using the oxygen and justifies the imposition of a $250 fine.

b) 7 MCAR § 1.049C.1.

This rule requires a patient to have an initial medical history and complete physical exam within specified periods of time and outlines the contents of the medical records. The information placed on the medical record is important for the health, safety and treatment of the patient since it provides the necessary information on which the medical care of the patient is based. It is important that the information be completed in the time period specified in the rules to assure that the patient is being adequately cared for in the facility. This rule also contains the amended requirements relating to the tuberculosis testing of patients

in the facility. The Department feels that a violation of this rule would jeopardize the health, safety and treatment of patients in a nursing home since insufficient or inappropriate information is provided to the facility for the necessary care of the patient. Thus, the Department feels that the imposition of the maximum fine of $250 per day is reasonable.

c) 7 MCAR § 1.064A.3.P.(1)(b).

This rule requires that the type of locks used on patient bedroom doors meet certain requirements. These requirements are based on the provisions of the Life Safety Code and are designed to assure prompt access to the room in the event of an emergency. The failure to comply with the provisions of this rule would create a situation jeopardizing the health and safety of the patients and, for the reason, the Department feels that the imposition of the maximum fine is reasonable.

7 MCAR Section 1.058 Allowable Time Periods For Correction

I General Comments

This proposed rule, which designates specific time periods for the nursing home to come into compliance with a correction order, is a new rule. The development of this rule is mandated by the provisions of Minnesota Statutes, 144A.10, subdivision 4. That statute specifies in part that "...the Commissioner of Health by rule shall establish a schedule of allowable time periods for correction of nursing home deficiencies." Thus, the necessity for the development of this proposed rule is clearly and specifically stated in the licensing statutes. It should be noted, that the proposed schedule of allowable time periods for correction only applies, at this time, to the specific rules that are subject to the April 1, 1980 hearing. The remaining nursing home rules will be given specific allowable time periods for correction at the time those rules are amended. It should also be noted that the provisions of Minnesota Statutes, § 144A.10, apply only to those facilities which are licensed as nursing homes. Thus, the provisions of this rule would not apply to facilities presently licensed as boarding care homes since those facilities are licensed and regulated under the provisions of Minnesota Statutes § 144A.50-122.56, and 144.653(1978).

There are two general sections to the provisions of 7 MCAR § 1.058. The first section, Section A, enumerates the specific time periods that will be allowed for correction of a nursing home deficiency. Section B, on the other hand, provides a mechanism by which the administrator of a nursing home can request an extension of a period of time for correction. This later section is necessary in order to provide the administrator with a mechanism to request an extension of time in situations where he can demonstrate that it was not possible to attain compliance

with the correction order in the period stated in the rules. A further analysis of the extension provisions will be discussed in detail, below.

The allowable time periods for correction were limited to three specific time categories, 14 days, 30 days, and 60 days. The reason for limiting the allowable periods of correction to these three categories was to establish a relatively uniform framework upon which the specific rules could be classified. The three categories also represent a reasonable attempt to provide sufficient time to the administrators of a facility to obtain compliance and when the provisions for extension of times are considered, the established time periods are not unreasonable.

The 14 day allowable time period for correction is used for those rules which can be easily corrected by a facility utilizing the internal resources of the nursing home. Thus, for those orders which can be corrected by the development of internal policies, or by utilizing the resources of the existing nursing home staff, the Department feels that a 14 day period to obtain compliance with the correction order is reasonable. In situations where the administrator can demonstrate to the Department that the period of time is not sufficient, the administrator would be allowed to request an extension of the specific time period for correction. It should also be pointed out, that the allowable time period for correction does not commence until the facility has received a copy of the correction order. The provisions of Minn. Stat. 144A.10 subd. 3, require that the correction orders be mailed to the facility by certified mail. Thus, the time period for correction will not commence to run until the facility receives the correction orders. However, the administrator and staff of the nursing home, even prior to the actual receipt of the written correction orders, have been informed of the Department's findings that were made during a survey. The Department is required to hold an

exit interview with the administrator and other facility staff to discuss the findings made during the survey of the facility and, at that time, the administrators are informed of the areas that will more than likely result in the issuance of a correction order. Thus, the administrators are given advance notice of the deficiencies found in the facility and steps to attain compliance with those correction orders should commence at that time.

The thirty day allowable time period for correction is utilized for those rules that, while possibly capable of being corrected through the utilization of nursing home resources, would usually require some contacts with individuals outside of the facility. In those situations where an order allows a thirty day period for correction, the facility has additional time to make the necessary internal arrangements as well as to contact people outside of the facility to assure that compliance is indeed attained within this period of time. The Department feels that the thirty day time period for these rules is reasonable and will provide the administrator of the facility sufficient time to make the necessary arrangements. Then, if the administrator can demonstrate that he has indeed actually been seeking to attain compliance and has run out of time, an extension may be granted under the requirements of the rule.

The third category of time, the sixty day/time limit, is reserved for those specific rules where outside resources would generally have to be contacted since the nursing home would not be expected to have internal resources to attain compliance. This section is generally used for those requirements which specify the purchasing of equipment or the obtaining of contracts to perform work on the physical plant structure of the facility. The sixty day time period would allow time for the administrator to obtain bids, to enter into contracts and, if necessary, also to

contact or seek the approval of the facility's board of directors for any sort of major repairs. Again, the Department feels that the sixty day time period would provide a reasonable amount of time to the administrator to make the necessary contacts and arrangements to obtain either the equipment or to make the arrangements for outside individuals to come in and to complete the work in the facility. Again, the administrator could request an extension of time if compliance could not be attained within sixty days.

It should be emphasized that the administrators of nursing homes are aware of the requirements that are contained in the existing licensing rules. Since the administrators have notice of the requirements that are expected of them, the ability of the administrator to operate the facility in compliance with these minimum standards at all times is to be considered the standard by which their operation is to be measured. However, the Department does indeed realize that it cannot be expected that the facility is continually operated in total compliance with the rules. However, the Department feels that when noncompliance with the rules is demonstrated by Department surveyors, it is incumbent upon the nursing home to immediately take the steps that will bring that facility into compliance with the provisions of the licensing rules. The 14 day, 30 day and 60 day time periods should allow sufficient time for the administrator to take the necessary steps to attain compliance and when coupled with the requirement that the facilities are expected to be operated at the minimum level at all times, these time periods do not put an undue burden upon the administrator of the facility. However, by developing a mechanism to request an extension of time based upon the examination of the efforts of the administrator, the Department has also recognized situations where compliance may not be attained within the period of time and has allowed the administrator to request extensions for good cause.

II. Specific Analysis of the rule

Section A of this rule contains the specific time periods allowed for the correction of the rules being proposed at the April 1, 1980 hearing. For purposes of easy reference, the various subsections of section A correspond to the elements contained in the substantive language of the rules. For example, the elements contained in 7 MCAR § 1.046 are assigned specific periods of time for correction under subsection 1. However, for the purpose of providing the justification for the elements contained in Section A., the rules will be grouped in accordance with the specific time periods assigned.

A. Fourteen Day Correction Orders

The licensing rules that have been assigned a fourteen day allowable period of time for correction are those rules which can be corrected through the utilization of resources within the nursing home. Since the underlying intent of the legislation authorizing the issuance of correction orders is to assure that violations of the licensing rules are corrected as soon as possible, the Department believes it is necessary to require that the administration of the nursing home take the necessary steps to assure that orders are completed as rapidly as possible. In situations where the corrections can be made by facility staff without requiring assistance from individuals not employed by the facility, the Department believes that the fourteen day period of time is reasonable. The rules which are assigned 14 days for correction can be corrected by the development of policies, by instructing or reminding staff of the requirements of the rules, by monitoring staff performance or by sending reminders to individuals outside of the facility, such as physicians, of the requirements of the rules. It should also be kept in mind that in some situations, particularly those involving records and recording keeping, it might not be possible to rectify the particular deficiency which resulted in the issuance of the correction order.

In those situations, compliance with the correction order would be verified by looking at records completed after the period of allowable time had elapsed to determine that similar deficiencies have not occurred. An example would be the requirements that are contained in 7 MCAR § 1.049 C.1. relating to the physician's documentation that the patient or resident is free from tuberculosis. Since this information is to be completed within specified periods of time, there is nothing that could be done to correct a deficiency noted during the review of a particular patient's record. However, the facility must assure that steps will be taken to prevent similar occurrences from happening with other new admissions and during the reinspection, it would be the records of the new admissions that would be reviewed. Thus, in situations where record-keeping requirements are required to be corrected within fourteen days, the fact that the facility will generally only be required to assure that similar occurrences do not arise in the future, make the 14 day period reasonable. The following rules have been assigned a fourteen day allowable period of time for correction:

7 MCAR § 1.046, sections L.2.b.; L.2.c.: L.2.d.: 1.2.e.: L.2.f

These sections relate to various provisions governing the administration of oxygen to patients in a nursing home. The particular sections require that physican orders be provided for those patients requiring the administration of oxygen, the development of policies assuring the safe and proper administration of oxygen, assuring that patients needing oxygen are informed of any limitations or restrictions; and assuring that training is provided to the nursing home staff. In each instance, the nursing home would be able to comply with a correction order issued under one of these rules through the internal resources of the facility.

A violation of the provisions of 7 MCAR § 1.046L.2.b., relating to the physician

orders, would be corrected through notification to the appropriate physicians of the requirements of the rule. The administration of oxygen is considered to be a treatment which requires the physician's written order and 14 days provides sufficient time in which to remind physicians of these requirements.

A violation of the provisions of 7 MCAR § 1.046L.2.c., relating to the development of policies by the Patient Care Policy Committee would be corrected by requiring the policy committee to either develop or to amend policies to assure that the required elements of this particular section are met. These policies are important to the health and safety of the patients and since the committee is already required by the provisions of MHD 45(h)(7), the 14 day time would provide sufficient time to comply with a correction order issued under this rule.

A violation of 7 MCAR § 1.046L.2.d., relating to the notification to patients of any limitations or restrictions, would be corrected by assuring that the staff is reminded of the requirements of this rule and by monitoring to assure that the information is provided to the appropriate patients. The 14 day time period provides adequate time to comply with a correction order issued under this rule.

A violation of 7 MCAR § 1.046L.2.e., relating to staff training, would be corrected by assuring that proper training is provided to the employees of the facility regarding the administration of oxygen. Correction would be attained by requiring the director of nursing in the facility to either provide the necessary training or to assess the capabilities of the nursing staff to see if additional training is required. It is already a responsibility of the director of nursing to provide orientation and in-service to the nursing staff (MHD 50(f)(3)) and the facility is required to have training programs established (MHD 45(h)(2)(ee) and MHD 50(d)). Thus, the facility is capable of complying with a correction order

within 14 days.

A violation of 7 MCAR § 1-046L.2.f., relating to the policies and procedures regarding the storage and cleaning of the oxygen supplies and equipment, would be corrected by contacting the appropriate personnel within the facility to either develop or revise policies and procedures to meet the requirements of these rules. Since the development or revision of the policies and procedures would be done by facility personnel, the 14 day time period is reasonable.

7 MCAR § 1.047 A

A violation of any of the provisions contained in 7 MCAR § 1.047A., relating to the tuberculosis testing of employees, would be corrected by informing staff of the requirements of this rule and by reviewing the personnel records of the facility to determine that any required tests are obtained. Compliance with the correction orders would be dependent on the actions of the facility staff, and for that reason, the 14 day time period is reasonable.

7 MCAR § 1.048A.4; A.8.b; A.8.c(4)(a); A.8.c(7); A.8.d.; A.8.e.

A violation of 7 MCAR § 1.048A.4., relating to the period of time for the retention of records, would be corrected by reminding the appropriate staff of the requirements of the rule and assuring that the practices of the facility are changed to reflect the rule requirements. Compliance could be obtained within a 14 day period.

A violation of the provisions of 7 MCAR § 1.048A.8.b.; relating to the written authorizations to handle the personal funds of patients and residents, would be corrected by informing the facility staff as to the requirements of the rule and monitoring new admissions to determine that the appropriate forms are completed. The 14 day period provides time to take these measures.

A violation of the provisions of 7 MCAR § 1.048A.8.c.(4)(a), relating to the access to a patient's or resident's financial records, would be corrected by the development of the policy required by this rule or by reminding facility staff as to the provisions of the established policy. Since compliance is dependent upon the actions of facility staff, the 14 day time period is reasonable.

A violation of the provisions of 7 MCAR § 1.048A.8.c(7), relating to a patient's

or resident's right to withdraw personal funds, would be corrected by developing a policy as required or by informing staff of the provisions of the policy. Since compliance is dependent upon the actions of facility staff, the 14 day time period is reasonable.

A violation of 7 MCAR § 1.048A.8.d. and e., relating to the requirements upon the discharge or death of patient or resident, would be corrected by informing staff of the requirements of these rules and monitoring performance to assure that the provisions of the rules are carried out. Compliance is dependent upon the actions of the facility staff and the 14 day time period is appropriate.

7 MCAR § 1.049C.1.

A violation of the provisions of 7 MCAR § 1.049C.1., would be corrected by informing physicians as to the requirements contained in the rule and monitoring new admissions to assure that the required information is submitted within the designated time periods. The notification and monitoring would be done by facility staff, and the 14 day time period would provide sufficient time to make these arrangements.

7 MCAR § 1.055U.1.b(2)(a); U.1.b.(2)(b); U.1.b(2)(c); U.1.b(2)(d); U.1.b(2)(e); &.1.b(2)(f); U.1.b(2)(g); U.1.b(2)(h); U.1.b.(2)(i)

The above sections reference the rule which allows for the use of low temperature/chemical sanitizing dishwashers. The sections referenced above specifically refer to the portion of that rule which relates to the operation of these dishwashers. In each instance, compliance with a violation would be attained by contacting the appropriate staff and reminding them as to the specific requirements contained in this rule. In addition, it might be necessary to monitor staff to assure that the required procedures are carried out. These sections require that the machine

be cleaned and operated in accordance with the manufacturer's instructions, that water temperature be maintained at the appropriate levels, that chemicals used for sanitizing are automatically dispensed, that the chemicals purchased bear labelling that they are registered in accordance with law, and that proper sanitary precautions are taken. Each of these requirements is dependent on the actions of the facility staff and the 14 day time period is a reasonable time for compliance.

7 MCAR § 1.064A.3.f(1)(b)

A violation of 7 MCAR § 1.064A.3.f(1)(b), relating to the types of locks that could be installed on patient bedroom doors,would be corrected by assuring that the facility takes the necessary steps to either install the correct types of locks, or by rendering the locking mechanisms inoperable, while waiting to obtain the necessary locks. A violation might also be based on the failure to have master keys available, which would be corrected by assuring that the necessary keys are located and properly distributed. The use of improper locks could create situations which jeopardize the health and safety of residents, and the facility must assure that only the proper locks are installed. Since this is a new requirement, a nursing home will generally take steps to assure that any lock installed after the effective date of this rule, meets these requirements. However, the Department must assure that a violation of this rule is complied with as soon as possible, and feels that the 14 day time period is reasonable.

B. Thirty day correction orders

The licensing rules that have been assigned a thirty day period of time are those rules which will require the assistance of individuals not employed by the nursing home. For that reason, the Department feels that additional time should be provided to comply with the provisions of these rules. These rules require the hiring of staff, the development of policies or procedures needing input from individuals other than employees, and assistance from persons outside of the facility. The following rules have been assigned a 30 day allowable period of time for correction:

7 MCAR § 1.046L.2.a.

A violation of this rule, which requires the provision of 24 hour licensed nurse coverage, would generally require the facility to hire additional staff to meet this requirement. For that reason, the Department feels that 30 days should be provided to allow the facility additional time to take the necessary steps relating to the hiring of new employees. The Department is aware of the difficulty that some homes are experiencing in obtaining licensed nursing staff; however, due to the need to assure that licensed staff are available in facilities which administer oxygen to protect the health and safety of patients, the Department feels that 30 days is a reasonable period of time to comply with this rule. The extension of time mechanism may be available to facilities which have difficulty in meeting this requirement.

7 MCAR § 1.048A.8.a.; A.8.c.(1); A.8.c.(2); A.8.c.(3); A.8.c.(4)(b); A.8.c.(4)(c); A.8.c.(5); A.8.c.(6); A.8.f.

These sections relate to portions of the rule governing the handling of the personal funds of patients and residents.

A violation of 7 MCAR § 1.048A.8.a. would require the development of a policy specifying whether or not the facility would handle the personal funds of residents or patients. While the development of the policy would be done by facility staff, the Department feels that it might be appropriate to discuss the development of this policy with the residents in the home. For that reason, the Department feels that additional time should be provided to allow for consultation with the patient, residents and other individuals.

A violation of 7 MCAR § 1.048c.(1)-(3), relating to the actual handling of the personal funds of residents or patients, would generally have to be corrected by establishing separate accounts for these funds to avoid commingling with the facility's moneys. For that reason, contacts with individuals outside of the facility will be required and the Department feels that the 30 day time period is reasonable.

A violation of 7 MCAR § 1.048A.8.c.(4)(b), relating to the provision of quarterly statements, would possibly require input from persons outside of the facility to assist in developing a mechanism to process and issue the quarterly statements. Thus, since assistance from outside the facility might be necessary, the Department feels that the 30 day time period is reasonable.

A violation of the provisions of 7 MCAR § 1.048A.8.c.(4)(c), relating to the record keeping requirements for personal funds, might also necessitate the assistance of individuals outside of the facility to assure that an efficient record keeping system is established. For that reason, the Department believes that the 30 day time period is reasonable.

A violation of 7 MCAR § 1.048A.8.c.(5) or (6) relating to the handling of funds in excess of $100 as well as the prorating of any accrued interest, would also

generally require assistance in complying with the provisions of a correction order. For that reason, the Department feels that the 30 day time period for attaining compliance would be reasonable.

A violation of 7 MCAR § 1.048A.8.f., relating to the requirements to be completed prior to a change of ownership, would also require the assistance of individuals outside of the facility. For that reason, the Department feels that the 30 day time period is reasonable.

7 MCAR § 1.052A.1.b.

A violation of 7 MCAR § 1.052A.1.b., relating to developing a policy regarding the use of double beds, would be corrected by assuring that the nursing home staff take the necessary steps to develop the policy. However, since input from the residents might be considered appropriate by the nursing home, the Department feels that the additional time provided by the 30 day time period is reasonable.

7 MCAR § 1.053F.2.

A violation of 7 MCAR § 1.053F.2., relating to the return of medications in accordance with the Board of Pharmacy rules, would be corrected by informing the facility staff of the requirements contained in this rule. However, since discussions with the facility's consultant pharmacist may be required to assure that proper procedures are developed, the Department feels that the 30 day period is reasonable.

7 MCAR § 1.055U.1.b.(1)(b); U.1.b.(1)(c)

A violation of 7 MCAR § 1.055U.1.b.(1)(b)&(c) relating to the audible signaling device and the correct pressure of the rinse water, would generally require the assistance of personnel from the manufacturer of the dishwashing machine. For that reason, the Department feels that the provision of 30 days to attain compliance is reasonable.

7 MCAR § 1.064A.3.f.(1)(a)

A violation of 7 MCAR 1.064A.3.f.(1)(a), relating to the development of a policy regarding the use of locks on patient bedroom doors, would require that facility staff take the necessary steps to develop this policy. However, since the nursing home might want to consider receiving input from the patients in the facility, the Department feels that the 30 day time period is reasonable.

C. Sixty day correction orders

The licensing rules that have been assigned a sixty day period to attain compliance are those rules which will require assistance from outside of the facility and will generally require the development of contracts or receipts of bids before the corrections could be made. The Department recognizes that the approval of contracts and receipts of bids is a lengthy process and feels that the provision of sixty days to attain compliance is reasonable. The rules that have been assigned a sixty day time period are as follows:

7 MCAR § 1.055U.1.b.(1)(a); U.1.b.(1)(d)

A violation of 7 MCAR § 1.055U.1.b.(1)(a), relating to the specific type of dishwasher, would generally require the facility to contact individuals and to obtain bids for the purchase of this item. For that reason, the Department feels that the 60 day time period is reasonable.

A violation of 7 MCAR § 1.055U.1.b.(1)(d), relating to the size of the clean dish counter, might involve the receipt of bids to determine the cost of making the necessary changes to comply with the requirements of this rule. For that reason, the Department feels that the 60 day time period is reasonable.

Section B. Extension of the allowable time period for correction.
This section outlines the procedures that are to be followed by the administrator if a request for an extension of time is necessary. The section indicates the procedures to be followed and the type of information to be supplied to the Department and also specifies in detail the criteria that the Department will use in evaluating the requests for the extension of time and procedures to notify the administrator of the Department's decision. This section also indicates that renewals of a request can be made and provides the steps that would be followed in a denial of a request for an extension of time.

Section B.1. Requests for extensions.
This rule provides that the administrator of the home may request an extension of time and requires that the request for extension be received by the Department prior the expiration of the time cited in the correction order. The rule then indicates that the failure of the facility to contact the Department and request an extension within the specified period of time would result in a denial of the request. The Department feels that the request should only be made by the administrator of the facility since it is the administrator's responsibility to assure that the correction orders are complied with in the appropriate time frames. The administrator is responsible for the performance of facility staff and he should be aware of reasons that would necessitate extension of time. In situations, where the administrator is not available, such as leave of absence or vacation, the existing nursing home rules require that the administrator designate an individual to be in charge of the facility. In those situations, the Department would recognize this fact and would accept requests for extension from an individual other than the administrator. The Department feels it is reasonable to require that the re-

quests for extension be received prior to the expiration of the time frame for correction since the basic purpose of the correction order system is to assure that the corrections are made in the quickest period of time. The rules provide for reasonable periods of time to attain compliance and the administrator of the facility is responsible for monitoring the staff's response to complying with the correction orders and should be in the position to determine when an extension might be appropriate. It should be noted that the rule indicates that the request must be received by the Department prior to the expiration of the specified time but does not indicate how the request must be received. Thus, the administrator could verbally request an extension of time as long as the request was made to the appropriate individuals within the specified time for correction. The portion of the rule indicating that a request received after the time period for correction had elapsed would result in a denial of an extension is reasonable due to the fact that there must be some mechanism to assure that facilities will not delay in making efforts to attain compliance based on an assumption that they could always request an extension at some time in the future. The rule has established reasonable time periods for correction, the administrators will be aware of these requirements and since the administrators are required to be aware of the activities of their staff, they should be in a position to determine when an extension would be required prior to the expiration of the specified period of time.

Section B.2.a. Contents of Request

This section of the rule outlines the information that is to be provided at the time a request for an extension of time is made. The rule requires that the administrator refer to the specific rule for which the extension of time is

requested, that the administrator provide the date that the correction order was received, the specified allowable period of time for correction, and indicating in detail the reasons for the request which would include the steps that have been taken to attain compliance, an indication of the additional time necessary to attain compliance and other information that the Department might request in order to evaluate the request for extension. These elements are necessary in order to assure that the Department is accurately informed of the specific correction order for which additional time is necessary, and to assure that the request for the extension is made within the appropriate time frame. While some of this information would also be available to Department personnel, the Department feels that it is reasonable to request this information from the administrator since verbal requests for extension can be submitted and it would provide for the information to be provided to the Department personnel being contacted as to the specific nature of the request and the particular rule being questioned. The Department feels that it is also reasonable to request that the reasons necessitating the extension be provided to the Department in detail, and that these reasons also specify the steps that the facility has taken to attain compliance. This particular requirement is necessary since the criteria used to evaluate the request will, in part, hinge upon the efforts that the facility has made to attain compliance. Without being provided a detailed statement as to the steps the facility has taken, it would not be possible to evaluate whether the facility has actually been operating in a good faith manner to attain compliance with the correction order. The Department feels that it is reasonable to request the additional amount of time that the administrator feels will be necessary to attain compliance since it will be the administrator who will be in the best position to determine the amount of time facility staff will need to make the necessary corrections. The administrator

will have this information available to him and it would be reasonable to assume that the administrator would be in a position to clearly indicate the additional time that would be necessary. The last category indicates that the Department has the right to request other relevant information that might be necessary in order to evaluate the request for an extension of time. The Department feels that such a general statement is reasonable to assure that the necessary information is available to the Department to properly evaluate the request for an extension of time. In certain situations the additional information might be the providing of names of individuals or firms that were contacted to make necessary repairs, copies of any sort of advertisements that might be placed in local newspapers as to employment opportunities, as well as possibly providing information that would demonstrate that the continued non-compliance with the rule would not jeopardize the facility's patients. Since the request for extensions will be based on individual circumstances, the Department feels that it is necessary to assure that all information relevant to the evaluation of the request can be obtained by the Department.

Section B.2.b.

This section states that if the request for extension is made orally, the administrator shall mail,within 24 hours, written confirmation containing the information specified in Section B.2.a. above. The Department feels that this rule is necessary to assure that a written record of the request will be provided and maintained on the facility's file and also to assure that there will be a written record upon which the Department's evaluation can be made. The Department feels that the 24-hour time limit is necessary to assure that the information will be promptly submitted to the Department, so that the evaluation of the request can be accurately and quickly made, thus requirement is reasonable when the intent of the law to assure that correction orders are complied

with in this period of time is considered. The administrator at the time of the oral request will have had the necessary information available and it would be not unreasonable to require that this information be put in writing and mailed to the Department within 24 hours after making the verbal request.

Section B.3. Criteria for evaluation.

This section outlines the criteria that will be used by the Department to evaluate the request for an extension. The basis for the criteria is found in the provisions contained in Minn. Stat. § 144A.04 subd. 3 (1978) as well as in Minn. Stat. § 144A.06 subd. 2. (1978). Those statutory provisions provide for a temporary waiver of compliance with one or more of the nursing home rules in situations where a facility is attempting to qualify for licensure (Minn. Stat. 144A.04) and in situations where a facility is undergoing a transfer of interest (Minn. Stat. § 144A.06). Those sections indicate that in certain situations, a facility could be issued a license even though there is not complete compliance with the licensing rules at the time the license is issued. The criteria established in the statute states that the waiver would be granted in situations where noncompliance will not create a risk of harm to the residents and upon demonstration that the controlling persons have entered into contracts to obtain the corrections, but for reasons other than the nursing home's failure, corrections have not been completed, or an indication that the facility is proceeding in a good faith manner to make the corrections. The criteria contained in the licensing rule is very similar. The first criteria indicates that the continued noncompliance will not jeopardize the health, treatment, comfort, safety or well being of the residents. The Department feels that this criteria is both necessary and reasonable in order to effectively demonstrate that the facility's ability to continue to remain in a state of noncompliance will

not create a situation which would jeopardize the health, treatment, comfort, safety or well being of the patient. Since the purpose of the correction order law is to assure that corrections are made as soon as possible, the Department must be assured that the extension of any time to attain compliance will not create a situation that would be harmful to the patients within the facility. The second criteria is necessary and reasonable since it assures that nursing home would receive an extension only in situations where steps have indeed been taken to come into compliance with the correction order but that total compliance cannot be attained within the stated period of time. The first part of the second criteria applies to situations where the administrator has entered into contracts to attain either materials, labor, personnel or the other items necessary to attain compliance, but that the supplier/contractor or other individual has failed to perform or is unable to perform within the time period specified. It also indicates that the inability of the nursing home to comply with the order is due only to that failure. The Department recognizes that there will be some situations when the nursing home has taken all of the appropriate steps to attain compliance such as the entering into contracts or other arrangements to assure that the orders are corrected but for a variety of reasons, the individuals who have agreed to make the repairs or to be employed by the facility, etc., cannot comply within the stated period of time. Upon demonstration that the criteria is met, the Department would allow for an extension of time. The second part of the second criteria would be a determination that the facility is making a good faith effort to comply with the correction order. There will also be some situations where the ability of a facility to attain compliance is not necessarily based on the entering into contracts or agreements with individuals outside the facility. In certain situations, such as the development of policies or pro-

vision of training to staff, if the facility can demonstrate that they have done everything possible to attain compliance but, for valid reasons have not yet been able to comply within the stated period of time, the Department would consider the request for an extension. The burden of demonstrating that the facility has been actively working in a good faith manner to attain compliance would be up to the facility and they would have to document what has been done and why compliance has not yet been attained. The good faith standard provides a means by which the facility can demonstrate the extent of their activities and is necessary to cover those situations where correction would not be attained through contracts or other arrangements with outside personnel.

In order for the Department to approve an extension of time, it should be noted that the criteria designated as 3.a.(1). must be met and that either section a. or section b. of criteria (2) must also be met. The two-part criteria is necessary to assure that continued extension of time would not be harmful or create a situation that could be harmful to residents and also to assure that extensions will only be granted in situations where the facility has demonstrated their ability to attain compliance with the correction orders.

Section B.3.b. Notification of decision.

This section indicates that the administrator shall be notified in writing of the Department's decision, and if granted, the notification shall also indicate the amount of time that will be provided. The Department feels that this rule is necessary in order to assure that there will be a written record indicating the reasons for which the extension was made and also to provide a written record of the additional time provided to the facility to attain compliance. This written record will be placed on the facility's file and it will also be used to

provide the administrator with an accurate record of the Department's decision. It should be noted that the amount of additional time given to the facility has not been specifically delineated in this particular section. The Department feels that there should be some discretion in specifying the additional time that will be provided. Since there may be many reasons for requesting an extension of time and since extensions of time could be requested for relatively short or somewhat extended periods, the Department feels that it would be more administratively efficient to have some flexibility in granting extensions for periods of time based upon the administrator's indication of how much time will be required to attain compliance, as well as on the Department's determination of whether or not that time period is reasonable. While the rule could specify that the extensions not exceed the time period specified in Section A of this rule, in some situations it might be very clear, at the time the request is made, that those time periods might not be sufficient. Thus, the Department feels it is reasonable that some discretion be provided in calculating the time for an extension and that the reasonableness is also emphasized by the fact that renewals of an extension can also be requested.

Section B.4. Renewal.

This section indicates that an administrator could request a renewal of an extension of time and provides that the requests are to be made in accordance with the instructions governing the initial request for extensions. Section b. also indicates that the approvals for the extension of time will be granted if the Department determines that the criteria contained in section B.3 are also met. The Department feels that it is necessary to have a section relating to the renewal of the extension of time due to the fact that there will be situations where facilities may still not be able to attain compliance even though an exten-

sion of the original period of time has previously been granted. In those situations, where a renewal is necessary, the administrator will still have to provide the same information in order to assure that there will be a thorough evaluation of the request. As with the request for initial extension, the Department will also be using the same criteria to evaluate the request in order to assure that the continued noncompliance will not create a situation which could jeopardize the health, safety, comfort and well being of the patients in these facilities, and to also assure that the facility has been actively working to attain compliance with the correction order. If the facility can meet the criteria, it would be reasonable for an extension to be granted. The criteria provides sufficient control in assuring that renewals would not be granted in situations where the facility has not been actively seeking correction of the nursing home deficiency.

Section B.5. Denial.

This section specifies that the Department will deny any request for an extension if the criteria contained in Section B.3 are not. The rule indicates that the denial shall be in writing and shall list the reasons for the denial. The rule is necessary in order to clearly indicate that the right to an extension of time is not going to be automatically granted. Again, this rule is reasonable when the premise behind the correction order system is considered which again require that corrections are to be made in the quickest possible period of time. If the administrator cannot demostrate to the Department's satisfaction that the criteria contained in Section B.3 are indeed met, the Department will deny the request for an extension on the grounds that continued noncompliance might pose a threat to the patients of the facility or based upon the determination that the facility has failed to actively take steps to attain compliance during the allowable period of

time contained in the correction order. The facility will not be provided a means to request an extension which would not be premised upon the fact that some activity had to be taken during the period of time from the receipt of the original correction order. The Department feels it is reasonable to require the denial be in writing and that the reasons for the denial be provided in writing to the administrator of the facility.

7 MCAR § 1.064 A.3.f. Bedroom Doors

I. General

In discussions before the LCRAR, both consumers and providers raised issues of privacy and security which they felt necessitated the repeal of the prohibition of locks on patient room doors. The LCRAR felt that the Life Safety Code (1976) regulations 10-2.2.8.1. and 10-3.2.8.1. adopted since the promulgation of the 1972 Department rule provides adequate safeguards and has recommended suspension of the rule.

The Department's concerns were and are based upon the need for immediate access to a patient's room in the event of an emergency, and to assure that staff is not prevented from entering a room to give necessary care. Delays occasioned by staff having to locate keys to unlock doors could seriously jeopardize safety of the patients if immediate evacuation became necessary. The prohibition also served to inhibit the locking of patients in their rooms in lieu of appropriate treatment.

In light of the LCRAR's suspension and the Nursing Home Advisory Council's recommendation that locks approved by the Life Safety Code be permitted, the Department is proposing repeal of the existing rule. In order to make certain that substantive provisions are inserted to protect the patients, the Department is proposing a new rule to assure that the nursing homes address these concerns.

II. Analysis of the Rule

7 MCAR § 1.064 A.3.f.(1)(a)

The Department recognizes the difficulties in providing privacy and security and at the same time assuring efficient provision of care and the avoidance of delay

in emergency situations. It believes that the most appropriate analysis of the various concerns must be made by each facility. The rule specifies that it is the facility's responsibility to develop a policy which allows for flexibility based on the needs of the home and the patient. The rule allows the facility to place limits on the use of locked doors such as when the door may be locked. The nursing home retains considerable flexibility in developing and implementing more specific policies and procedures. In addition, the facility has the option of banning the use of locks on patient bedroom doors.

7 MCAR § 1.064 A.3.f.(1)(b)

It is necessary to specify the type of lock permitted in order to assure for prompt access to the room. The rule is consistent with the locks approved by the Life Safety Code (1976) regulations 10-2.2.8.1. and 10-3.2.8.1. for nursing homes and boarding care homes. For the safety of the resident, the door must be openable from the inside at all times without the use of a key. This also assures that locks are not used inappropriately as a restraint or for punishment. The master key must be available at each nursing station to assure that staff will have prompt access to the locked room when necessary. The key may not be carried by any one individual since that person may not always be available when the access is needed.

STATEMENT OF COMPLIANCE WITH

RULE MAKING PROCEDURES

I, Special Assistant Attorney General John A. Breviu, do hereby declare that I have examined the proposed rules relating to Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes and all related documents and that, based on such examinations and my personal familiarity with the applicable procedures, the Rule Making Procedures have been followed.

Dated: October 10, 1980

John A. Breviu

JOHN A. BREVIU
Special Assistant
Attorney General

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes

NOTICE OF HEARING

A public hearing concerning the proposed amendments to the rules captioned above will be held in Room 105, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, on April 1, 1980, commencing at 9:30 AM. The proposed rules may be modified as a result of the hearing process. Therefore, if you are affected in any manner by the proposed rules you are urged to participate in the rule hearing process.

Following the agency's presentation at the hearing, all interested or affected persons will have an opportunity to ask questions and make comments. Statements may be made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted to George Beck, Hearing Examiner, Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, telephone: (612) 296-8108, either before the hearing or within five working days after the close of the hearing. The Hearing Examiner may, at the hearing, order that the record be kept open for a longer period not to exceed 20 calendar days. All such statements will be entered into and become part of the record. For those wishing to submit written statements or exhibits, it is requested that at least two (2) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The rule hearing procedure is governed by Minn. Stat. §§ 15.0411, 15.0417, and 15.052, and by 9 MCAR §§ 2.010-2.112 (Minnesota Code of Agency Rules). If you have any questions about the procedure, call or write the Hearing Examiner.

Twenty-five (25) days prior to the hearing, a Statement of Need and Reasonableness will be available for review at the agency and at the Office of Hearing Examiners. This Statement of Need and Reasonableness will include all of the evidence which the agency intends to present at the hearing to justify both the need for and the reasonableness of the proposed rule. However, additional evidence may be submitted in response to questions raised by interested persons. You are therefore urged to both review the Statement of Need and Reasonableness before the hearing and to attend the hearing. Copies of the Statement of Need and Reasonableness may be obtained from the Office of Hearing Examiners at a minimal charge.

A copy of the proposed rules is attached hereto and made a part hereof. The statutory authority of the Commissioner of Health to adopt these rules is contained in Minn. Stat. §§ 144.56, 144A.08, and 144A.10 (1978).

Any person may request notification of the date on which the Hearing Examiner's report will be available, after which date the agency may not take any final action on the rules for a period of five working days. Any person may request notification of the date on which the hearing record has been submitted or resubmitted to the Attorney General by the agency. If you desire to be so notified, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the Hearing Examiner, in the case of the Hearing Examiner's report, or to the agency, in the case of the agency's submission or resubmission to the Attorney General.

Minn. Stat. Ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five days after he or she commences lobbying. A lobbyist is defined in Minn. Stat. § 10A.01, subd. 11, (Supp. 1979) as any individual:

(a) Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any mohth or more than $250, not including his own travel expenses and membership dues, in any year, for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials; or

(b) Who spends more than $250, not including his own traveling expenses and membership dues, in any year for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, telephone: (612) 296-5615.

Dated: February 11, 1980

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

George R. Petterson M D

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

HLTH-80-040-GB

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes.

ORDER OF THE CHIEF HEARING EXAMINER

WHEREAS, a hearing was held on Tuesday, April 1, 1980, before George A. Beck, a Hearing Examiner of the State Office of Administrative Hearings, on the above-entitled matter in compliance with Minn. Stat. § 15.0412, subd. 4; and

WHEREAS, the Report of Hearing Examiner made pursuant to Minn. Stat. § 15.052, subd. 3, was issued to the Commissioner of Health and;

WHEREAS, the Commissioner of Health has now determined to adopt rules pursuant to Minn. Stat. § 15.0412, subd. 4; and

WHEREAS, the Commissioner of Health has submitted said rules to the Chief Hearing Examiner for review pursuant to Minn. Stat. § 15.052, subd. 4, and 9 MCAR § 2.110; and

WHEREAS, the Chief Hearing Examiner finds that the final proposed rules are not substantially different from those proposed at the public hearing and that the Department of Health has met all requirements of Minn. Stat. § 15.0412, subd. 4.

NOW, THEREFORE, upon receipt of this Order, the Commissioner of Health has the responsibility of submitting the complete hearing record and the rules as adopted by the Commissioner of Health to the Attorney General and to publish in the State Register, all pursuant to Minn. Stat. § 15.0412, subd. 4.

Dated: October 10th, 1980.

DUANE R. HARVES
Chief Hearing Examiner

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

In the Matter of Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes

AFFIDAVIT OF RECEIPT OF THE SECRETARY OF STATE'S LIST

Nancy Younger, being first duly sworn upon oath, deposes and says:

1. The she is an employee of the Minnesota Commissioner of Health.

2. That on the 19th day of February, 1980, she called the Minnesota Secretary of State's office and requested a current list of all representatives of associations or other interested groups or persons who had registered their names with the Secretary of State for the purpose of obtaining notices of public hearings relating to the promulgation of rules or amendments thereto pursuant to Minn. Stat. § 15.0412, subd. 4 (1978).

3. That on the 21st day of February, 1980, in response to the above request, the Secretary of State provided her with such a list, a photocopy of which is attached hereto and incorporated by reference.

Further affiant sayeth not.

Nancy Younger
NANCY YOUNGER

Subscribed and sworn to before me
this 25th day of February, 1980

FREDERICK L. KING
WASHINGTON COUNTY
NOTARY PUBLIC-MINNESOTA
MY COMMISSION EXPIRES FEB. 22, 1984

STATE OF MINNESOTA

COUNTY OF RAMSEY

In the Matter of Proposed Amendments
Relating to Rules for the Construction,
Equipment, Maintenance, Operation and
Licensing of Nursing Homes and
Boarding Care Homes

CERTIFICATE

I hereby certify that the 337 general labels and 9 page list for the Minnesota Commissioner of Health, all of which are attached and made a part hereof, constitute the complete lists of persons, associations, and other interested groups who as of 2:40 o'clock P.m., this 21st day of February, 1980, have requested, pursuant to Minn. Stat. § 15.0412, subd. 4 (1978), that their names be placed on file with the Secretary of State for the purpose of receiving notice of public hearing on proposed rules and amendments thereto on the subject captioned above.

SECRETARY OF STATE

JOAN ANDERSON GROWE

Joan Anderson Growe

By Donna M. Scott

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

In the Matter of Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes

AFFIDAVIT OF MAILING

Julie Erickson, being first duly sworn, deposes and says:

That on the 26th day of February, 1980, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Hearing by depositing in the United States mail at said City of Minneapolis, a true and correct copy thereof, properly enveloped, with postage prepaid, to all persons and associations at the addresses listed on the Certificate of the Secretary of State attached and made a part hereof as Exhibit A, to all nursing homes and boarding care homes at the addresses listed on Exhibit B, attached and made a part hereof, to all persons and associations at the addresses listed on Exhibit C, attached and made a part hereof, as well as to all members of the Minnesota Legislature as of the date of mailing.

Julie Erickson

Subscribed and sworn to before
me this 27th day of February, 1980.

FREDERICK L. KING
WASHINGTON COUNTY
NOTARY PUBLIC-MINNESOTA
MY COMMISSION EXPIRES FEB. 22, 1984

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the Proposed Amendments Relating to Rules for the Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes

ORDER FOR HEARING

To effectively implement Minn. Stat. §§ 144.56, 144A.08, and 144A.10 (1978), the Minnesota Commissioner of Health deems it necessary to consider adoption of the proposed amendments captioned above pursuant to the authority vested in him by the above-referenced statutes.

NOW, THEREFORE, IT IS ORDERED this 11th day of February, 1980, that a public hearing on the proposed rules captioned above be held in Room 105, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, on April 1, 1980, commencing at 9:30 AM, and continuing until all persons or representatives of associations or other interested groups have had an opportunity to be heard.

IT IS FURTHER ORDERED that notice of said hearing be published in the State Register and be given to all persons or representatives of associations or other interested groups who have registered their names with the Secretary of State for that purpose and to all persons who are presently members of the Minnesota Legislature.

STATE OF MINNESOTA

COMMISSIONER OF HEALTH



GEORGE R. PETTERSEN, M.D.
Commissioner of Health

Exhibit B

2. Rules relating to the transfer of patient's x-ray records. Contact: Dr. Ellen Z. Fifer
Assistant Commissioner for Programs
Phone: (612) 296-5391

3. Rules relating to the nature and requirements of all general formal and informal procedures (as distinguished from procedures for specific programs which will be promulgated as separate rules) related to the administration of official duties of the State Department of Health and the State Board of Health which directly affect the rights of or procedures available to the public.
Contact: Michael Moen
Phone: (612) 296-5463

Any materials submitted shall be reviewed and considered by the Department of Health during the preparation of the proposed rules. Notice of the public hearing on the proposed rules shall be published in the State Register and given to all interested parties who have registered with the Secretary of State's Office in accordance with the provisions of the Administrative Procedure Act.

Under the provisions of Minn. Stat. § 10A.01, subd. 11 (1974), any individual representing persons or associations attempting to influence administrative action, such as the promulgation of these proposed rules, must register with the State Ethics Commission as a lobbyist within five days of the commencement of such activity by the individual. The State Ethics Commission is located at Room 401, State Office Building, Saint Paul, Minnesota 55155.

Warren R. Lawson, M.D.
Secretary and Executive Officer

Department of Health
State Board of Health
Amendments to Rules Regulating the Operations of Health Facilities

Notice of Intent to Solicit Outside Opinion

Notice is hereby given, pursuant to the provisions of Minn. Stat. § 15.0412, subd. 6 (Supp. 1975) that the Minnesota State Board of Health will propose the adoption of new rules and the amendment and revision of existing rules.

All interested parties desiring to submit data or views relating to the proposed adoption, amendment or revision of the rules noted below should address their comments (either written or oral) to the Minnesota Department of Health, Division of Health Facilities, 717 Delaware Street S.E., Minneapolis, Minnesota 55440, by writing or calling the persons designated. Evidence submitted for consideration should be pertinent to the matter at hand. Written material received by the Department of Health will become part of the hearing record

1. Rules implementing the provisions of Laws of 1976, ch. 173, relating to the licensing and regulation of nursing homes. Contact: H. Michael Tripple
Phone: (612) 296-5418

2. Proposed amendments to MHD 391-410, Supervised Living Facilities, and to MHD 411-430, Out-patient Surgical Centers, with respect to the establishment of levels of assessments for violations of rules pursuant to Minn. Stat. § 144.653. Contact: H. Michael Tripple
Phone: (612) 296-5418

3. Rules relating to implementation of hospital rate review by the State Board of Health to include financial reporting requirements, rate review procedures, standards for approval of voluntary rate review procedures and establishment of a filing fee to be charged for submission of hospital rate modifications to the Board.
Contact: Kent E. Peterson
Phone: (612) 296-5365

4. Rules implementing Laws of 1976, ch. 325, relating to complaint or grievance mechanisms in hospitals, outpatient surgery centers, and health maintenance organizations. Contact: Janet G. Brodahl
Phone: (612) 296-5441

5. Rules relating to the establishment and approval of education courses in the health related subject of administration of medications by unlicensed personnel in health facilities. Contact: Robert A. Hamilton
Phone: (612) 296-5487

6. Proposed amendments to MHD 44 to 71, rules for the construction, equipment, maintenance, operation and licensing of boarding care homes, for establishing standards

for noncertified boarding care homes, and for establishment of levels of assessments for violation of the rules.
Contact: H. Michael Tripple
Phone: (612) 296-5418

7. Proposed amendments and rewriting of MHD 74-71, rules for the construction, equipment, maintenance, operation and licensing of nursing homes and boarding care homes, in addition to establishing standards for certified boarding care homes, and establishing levels of assessments for violations of the rules.
Contact: H. Michael Tripple
Phone (612) 296-5418

8. Rules relating to procedures for review of assessment hearings of all health care facilities.
Contact: H. Michael Tripple
Phone: (612) 296-5418

9. Proposed amendments to and rewriting of MHD 76-116, rules for the construction, equipment, maintenance, operation and licensing of hospitals, and for the establishment of levels of assessments for violations of the rules.
Contact: Daniel McInerney
Phone: (612) 296-5511

10. Rules relating to the award of emergency medical services grants. Contact: Bernard Webber
Phone: (612) 296-5281

11. Proposed amendments to MHD 391-410, Supervised Living Facilities, to include but not be limited to adding detoxification centers as a facility covered by these rules. Contact: Hans Larsen
Phone: (612) 296-5451

12. Rules relating to the "reasonable volume of uncompensated care" and the "community services" requirements of the hospital survey and construction (Hill-Burton) program.
Contact: Robert Manske
Phone: (612) 296-5442

Any materials submitted shall be reviewed and considered by the Department of Health during the preparation of the proposed rules. Notice of the public hearing on the proposed rules shall be published in the State Register and given to all interested parties who have registered with the Secretary of State's Office in accordance with the provisions of the Administrative Procedure Act.

Under the provisions of Minn. Stat. § 10A.01, subd. 11 (1974), any individual representing persons or associations attempting to influence administrative action, such as the promulgation of these proposed rules, must register with the State Ethics Commission as a lobbyist within five days of the commencement of such activity by the individual. The State Ethics Commission is located at Room 401, State Office Building, Saint Paul, Minnesota 55155.

Warren R. Lawson, M.D.
Secretary and Executive Officer

Minnesota Housing Finance Agency

American Indian Housing

Notice of Extension of Emergency Rules

Notice is hereby given that the Minnesota Housing Finance Agency's Emergency Rules Governing American Indian Housing, published at 1 S. R. 208-09, have been extended, as published, for an additional 75 day period, dated from the date of the order readopting the said rules and the refiling of said rules with the Secretary of State, October 26, 1976, pursuant to authority vested in me by the Board of the Agency, pursuant to Resolution of the Board, under the provisions of Laws of 1976, ch. 254, § 9 and as authorized by Minn. Stat. § 15.0412, subd. 5.

James F. Dlugosch
Executive Director

Pollution Control Agency

Proposed Rules Governing Installation and Operation of Individual Sewage Treatment Systems

Notice of Intent to Solicit Outside Opinion

Notice is hereby given that the Minnesota Pollution Control Agency (MPCA) has begun consideration of proposed

RECEIVED
FEB 27 1980
HEALTH SYSTEMS DIVISION
NOTICE: This material may be protected by copyright law (Title 17 U. S. Code)

TITLE 13 TAXATION
Part 1 Revenue Department
13 MCAR §§ 1.0021-1.0026 (proposed temporary) 1169
TITLE 14 TAXATION
Part 1 Transportation Department
14 MCAR § 1.3027 (proposed) 1393
14 MCAR §§ 1.4000-1.4005 (proposed 1204
14 MCAR § 1.4001 (Errata) 1255
14 MCAR §§ 1.4006-1.4009 (proposed) 1204

PROPOSED RULES

Pursuant to Minn. Stat. § 15.0412, subd. 4, agencies must hold public hearings on proposed new rules and or proposed amendment of existing rules. Notice of intent to hold a hearing must be published in the *State Register* at least 30 days prior to the date set for the hearing, along with the full text of the proposed new rule or amendment. The agency shall make at least one free copy of a proposed rule available to any person requesting it.

Pursuant to Minn. Stat. § 15.0412, subd. 5, when a statute, federal law or court order to adopt, suspend or repeal a rule does not allow time for the usual rulemaking process, temporary rules may be proposed. Proposed temporary rules are published in the *State Register*, and for at least 20 days thereafter, interested persons may submit data and views in writing to the proposing agency.

Department of Health

Proposed Amendments to Rules for Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes

Notice of Hearing

A public hearing concerning the proposed amendments to the rules captioned-above will be held in Room 105, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota, on April 1, 1980, commencing at 9:30 a.m. The proposed rules may be modified as a result of the hearing process. Therefore, if you are affected in any manner by the proposed rules you are urged to participate in the rule hearing process.

Following the agency's presentation at the hearing, all interested or affected persons will have an opportunity to ask questions and make comments. Statements may b made orally and written material may be submitted. In addition, whether or not an appearance is made at the hearing, written statements or material may be submitted to George Beck, Hearing Examiner,

Public Hearings on Agency Rules March 3-10, 1980

Date	Agency and Rule Matter	Time & Place
March 4	Transportation Dept. Implementation of MN Rail Service Improvement Program Hearing Examiner: Harry S. Crump	10:00 a.m., Rm. 125, State Capitol Bldg., St. Paul, MN
March 5	Transportation Dept. Rail User Loan Guarantee Program Hearing Examiner: Harry S. Crump	same as above

Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, telephone (612) 296-8108, either before the hearing or within five working days after the close of the hearing. The hearing examiner may, at the hearing, order that the record be kept open for a longer period not to exceed 20 calendar days. All such statements will be entered into and become part of the record. For those wishing to submit written statements or exhibits, it is requested that at least two (2) copies be furnished. In addition, it is suggested, to save time and avoid duplication, that

KEY: RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language. PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material."

those persons, organizations, or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement in behalf of such interests. The rule hearing procedure is governed by Minn. Stat. §§ 15.0411, 15.0417, and 15.052, and by 9 MCAR §§ 2.010-2.112 (Minnesota Code of Agency Rules). If you have any questions about the procedure, call or write the hearing examiner.

Twenty-five (25) days prior to the hearing, a Statement of Need and Reasonableness will be available for review at the agency and at the Office of Hearing Examiners. This Statement of Need and Reasonableness will include all of the evidence which the agency intends to present at the hearing to justify both the need for and the reasonableness of the proposed rule. However, additional evidence may be submitted in response to questions raised by interested persons. You are therefore urged to both review the Statement of Need and Reasonableness before the hearing and to attend the hearing. Copies of the Statement of Need and Reasonableness may be obtained from the Office of Hearing Examiners at a minimal charge.

A copy of the proposed rules is attached hereto and made a part hereof. The statutory authority of the Commissioner of Health to adopt these rules is contained in Minn. Stat. §§ 144.56, 144A.08, and 144A.10 (1978).

Any person may request notification of the date on which the hearing examiner's report will be available, after which date the agency may not take any final action on the rules for a period of five working days. Any person may request notification of the date on which the hearing record has been submitted or resubmitted to the Attorney General by the agency. If you desire to be so notified, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the hearing examiner, in the case of the hearing examiner's report, or to the agency, in the case of the agency's submission or resubmission to the Attorney General.

Minn. Stat. ch. 10A requires each lobbyist to register with the State Ethical Practices Board within five days after he or she commences lobbying. A lobbyist is defined in Minn. Stat. § 10A.01, subd. 11, (supp. 1979) as any individual:

(a) Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any month or more than $250, not including *his own* travel expenses and membership dues, in any year, for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials; or

(b) Who spends more than $250, not including *his own* traveling expenses and membership dues, in any year for the purpose of attempting to influence legislative or administrative action by communicating or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota 55155, telephone: (612) 296-5615.

February 11, 1980

George R. Pettersen, M.D.
Commissioner of Health

Amendments as Proposed

7 MCAR § 1.044 ~~MHD 44~~ Definitions, general provisions, issuance of licenses.

X. Variance and waivers.

1. General provisions. A nursing home or boarding care home may request that the department grant a variance or waiver from the provisions of these rules.

2. Contents of request. All requests for a variance or waiver shall be submitted to the department in writing. Each request shall contain the following information:

a. The specific rule or rules for which the variance or waiver is requested;

b. The reasons for the request;

c. The alternative measures that will be taken if a variance or waiver is granted;

d. The length of time for which the variance or waiver is requested;

e. Such other relevant information which the department shall determine is necessary to properly evaluate the request for the variance or waiver.

3. Criteria for evaluation.

a. A variance or waiver shall be granted if the department determines that:

(1) The alternative measures to be taken are equivalent or superior to those prescribed in the rule or rules;

(2) The granting of the variance or waiver will not adversely affect the health, treatment, comfort, safety or well-being of the patients or residents; and

(3) The application of the rule or rules would impose an undue burden upon the applicant.

b. The applicant shall be notified in writing of the department's decision. If a variance or waiver is granted, the notification shall specify the period of time for which the variance or waiver will be effective and the alternative measures or conditions, if any, to be met by the applicant.

4. Effect of alternative measures or conditions. All alternative measures or conditions attached to a variance or waiver shall have the force and effect of the licensure rule(s) and shall be subject to the issuance of correction orders and penalty assessments in accordance with the provisions of Minn. Stat. §§ 144.653 and 144A.10. The period of time for correction and the amount of fines specified for the particular rule for which the variance or waiver was requested shall apply.

5. Renewal.

a. Any request for the renewal of a variance or waiver shall be submitted in writing prior to its expiration date. Renewal requests shall contain the information specified in 2. above.

b. A variance or waiver may be renewed by the

department if the applicant continues to satisfy the criteria contained in 3. above and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance or waiver was granted.

6. Denial, revocation or refusal to renew. The department shall deny, revoke or refuse to renew a variance or waiver if it is determined that the criteria specified in 3. above are not met. The applicant shall be notified in writing of the decision to deny, revoke or refuse to renew and informed of the right to appeal this decision.

7. Appeal procedure. An applicant may contest the denial, revocation or refusal to renew a variance or waiver by requesting a contested case hearing under the provisions of the Administrative Procedures Act, Minn. Stat. §§ 15.0411 *et seq.* The applicant shall submit, within 15 days of the receipt of the department's decision, a written request for a hearing. The request for hearing shall set forth in detail the reasons why the applicant contends the decision of the department should be reversed or modified. At the hearing, the applicant shall have the burden of proving that it satisfied the criteria specified in 3. above.

7 MCAR § 1.046 ~~MHD 46~~ General policies.

L. ~~(1)~~ Use of oxygen.

1. Oxygen~~, when~~ may be used in a nursing home ~~shall be~~ on an emergency basis. ~~only. The oxygen shall be ordered by a physician.~~ A registered nurse or other person trained in the use of oxygen shall be responsible for its administration and shall be on duty during the entire time that oxygen is administered. The following precautions shall be taken:

a. ~~(1)~~ Signs indicating "No Smoking" shall be placed at the bedside and at the entrance to the room.

b. ~~(2)~~ All matches, ash trays and other smoking material shall be removed and kept out of the room.

c. ~~(3)~~ No oil or grease shall be used on oxygen equipment.

d. ~~(4)~~ Oxygen tanks shall be securely anchored when stored or in use.

2. A nursing home which admits or retains patients in need of oxygen, on other than an emergency basis, shall comply with the following provisions:

a. The nursing home shall provide 24-hour licensed nurse coverage, unless it only admits patients who can self-administer oxygen.

b. The patient's attending physician shall submit written orders for oxygen and, if self-administration of oxygen is also ordered, the physician shall specify that the patient is mentally and physically capable of administering oxygen without the assistance of the nursing home staff.

c. The Patient Care Policy Committee shall develop and implement written policies regarding the provision of oxygen in the nursing home. These policies shall, at a minimum, include:

(1) Any limitations placed on the patient or other patients such as room assignments and smoking policies.

(2) Any restrictions placed on patients using portable oxygen equipment as to mobility within the facility or participation in activities.

(3) A mechanism to periodically assess those patients authorized to self-administer oxygen as to their continued capability to self-administer it.

(4) Precautions to be taken, in addition to those in 1.a.-d., above, to assure the safe use of oxygen.

d. All nursing homes which admit patients in need of oxygen shall inform these patients of any limitations or restrictions imposed by the nursing home prior to admission or at the time the use of oxygen is ordered by the physician.

e. The director of nursing shall be responsible for providing training to the nursing home staff regarding the procedures to be followed for the administration of oxygen, for monitoring the use and effectiveness of oxygen, special precautions to be taken, and the care and cleaning of equipment.

f. Written policies and procedures shall be developed and implemented regarding the care, storage, cleaning and sanitizing of oxygen tanks, equipment and supplies.

7 MCAR § 1.047 ~~MHD 47~~ Personnel.

A. ~~(a) Annual Tests. All employees shall, prior to employment and annually thereafter, show freedom from tuberculosis by a report of either a standard Mantoux tuberculin test or a chest X-ray. If the Mantoux test is positive or contraindicated, a chest X-ray shall be taken. The results of these tests shall be reported in writing and made a part of the employee's personnel record. (See Personnel Records, under Records and Reports, MHD 48.)~~ Tuberculosis testing of employees. The nursing home or boarding care home shall be responsible for assuring that all employees, prior to employmen, and as otherwise indicated in this rule, show freedom from tuberculosis in accordance with the provisions of this section. The nursing home and the boarding care home shall reimburse their employees for the costs, if any, of obtaining the necessary tests which demonstrate freedom from tuberculosis.

1. All employees, unless certified in writing by a physician to have had a positive reaction to a standard intradermal tuberculin test, shall have a standard intradermal tuberculin test with purified protein derivative (Mantoux) within 45 days prior to employment.

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a. If the tuberculin test is negative, the employee shall be considered free from tuberculosis;

b. If the tuberculin test is positive or if the employee's physician has certified a positive reaction to the tuberculin test, the employee shall submit prior to employment and annually thereafter a written report by a physician of a negative full-sized chest X-ray taken within the previous 45 days. Annual written reports of the employee's negative chest X-ray shall be required for five years after a documented positive standard intradermal tuberculin test, after which time the employee shall be considered free from tuberculosis.

2. All employees showing positive reaction to the tuberculin test who have taken a complete course of preventive therapy as directed by their physician shall be considered free from tuberculosis at the completion of the program and shall be exempt from the testing requirements of this section.

3. Written documentation of compliance with the above requirements shall be filed in the employee's personnel record.

7 MCAR § 1.048 ~~MHD 48~~ Records and reports. [Applies to both nursing homes and boarding care homes.]

A. ~~(a)~~ Patient or resident care record. An individual chart shall be kept on each patient and resident admitted to the home. All entries shall be made with a pen and signed by the person making the entry. Accurate, complete and legible records for each patient or resident from the time of admission to the time of discharge or death shall be kept current and shall be maintained in a chart holder at the nurses' or attendants' station.[1]

1. ~~(1)~~ Admission record. The admission record shall be initiated for each patient and resident within 72 hours after admission and contain identifying information including: name, previous address, social security number, sex, marital status, age, date and place of birth, previous occupation, date and hour of admission; name, address and telephone number of the nearest relative, and the person to be notified in an emergency or death; information as to funeral arrangements, if available; church affiliation and pastor; and the name of the patient's or resident's attending physician. At the time of discharge or death, this record shall be completed with the date, time, reason for discharge, discharge diagnosis and condition; or date, time and cause of death. In either case the signature and address of the responsible person to whom released shall be obtained.

2. ~~(2)~~ Medical record. The medical record shall be initiated for each patient or resident within 72 hours in accordance with 7 MCAR § 1.049 C.

3. ~~(3)~~ Filing and disposition of records. The patient or resident care record shall be incorporated into an individual folder and filed at the nurses' or attendants' station.[1] The records of discharged patients or residents shall be promptly completed and filed in the home.

Patients' or residents' medical records and patient care plans in nursing homes shall be considered confidential but they shall be made available to all persons in the home who are responsible for the care of the patient or resident and they shall be open to inspection by representatives of the department. When a patient or resident is discharged to another care facility pertinent information relative to his care shall accompany the patient or resident

4. ~~(4)~~ Storage and preservation of records. Space shall be provided for the safe storage of patients' or residents' records at the nurses' or attendants' station[1] and in general storage. Records shall be filed so as to be readily accessible. All patients' and residents' records shall be preserved for a period of at least ~~ten (10)~~ 5 years following discharge or death.

5. ~~(5)~~ Census register. A register shall be kept in a separate bound book, listing in chronological order the names and dates of all admissions and discharges. This register shall be kept in such a manner that total admissions, discharges, deaths and patient or resident days can be calculated.

6. ~~(6)~~ Reports to the department. Reports regarding statistical data and services furnished shall be submitted on forms furnished by the department. Copies shall be retained by the home.

7. ~~(7)~~ Correspondence with department. All correspondence with the department shall be kept as a permanent, accessible record.

8. ~~(8)~~ Record of patients' and residents' funds. ~~The home shall keep a record of any personal funds, regardless of source, and of any valuables kept for a patient or resident. If purchases are made from these personal funds, proper receipts shall be kept and notations made in a separate bookkeeping system.~~

a. Admission agreement. The admission policies of the nursing home and boarding care home shall specify whether the home will accept the personal funds of patients or residents for safekeeping. If the nursing home or boarding care home accepts the personal funds of patients and residents for safekeeping, written policies regarding the handling and protection of the funds shall be established in accordance with this section.

b. Authorization.

(1) The personal funds of the patient or resident shall not be accepted for safekeeping without written authorization from the patient or resident or from the patient's or resident's legal guardian or conservator.

(2) A copy of this written authorization shall be retained in the patient's or resident's records.

c. Personal fund accounts.

(1) The personal funds of patients and residents shall not be commingled with the funds of the nursing home or boarding care home or with the funds of any person other than patients or residents of the home, unless otherwise authorized by law.

[1]A central control point for the storage of records and medications.

(2) The personal funds of patients and residents shall not be used in any way for the purpose of the nursing home, boarding care home or any other patient or resident and shall be free from any liability that the nursing home or boarding care home incurs.

(3) A person, firm, partnership, association or corporation which operates more than one facility licensed in accordance with the provisions of Minn. Stat. §§ 144.50-.56 or Minn. Stat. ch. 144A shall not commingle patient or resident funds from one facility with another.

(4) A written accounting system for the personal funds of patients and residents shall be developed and maintained.

(a) Each patient or resident and the patient's or resident's guardian, conservator, or other person designated by the patient or resident shall be allowed access to the written records of all financial arrangements and transactions involving the individual patient's or resident's funds in accordance with the nursing home's and boarding care home's written policy. Such policy shall assure that access be allowed at least one hour 5 days per week.

(b) Each patient or resident or the patient's or resident's guardian, conservator or other person designated in writing by the patient or resident shall be provided a written quarterly accounting of the financial transactions made by or on behalf of the patient or resident.

(c) An individual written record shall be maintained for each patient or resident which shall include the following items:

(i) The date, amount and source of funds deposited by or on behalf of a patient or resident.

(ii) The name of all individuals, other than the patient or resident, authorized to withdraw or expend funds from the patient's or resident's personal account.

(iii) The date and the amount of all withdrawals from the patient's or resident's personal account. Receipts for purchases made with money withdrawn from a patient's or resident's account by individuals other than the patient or resident shall be obtained and placed in the patient's or resident's record.

(5) The personal funds of any patient or resident in excess of $10,000 shall be deposited in a demand account in a financial institution authorized to do business in Minnesota, the deposits of which are federally insured, except that a facility that is operated by a county shall deposit such funds with the county treasurer. This account must be in a form which clearly indicates that the facility has only a fiduciary interest in the funds. Records shall be maintained which specify on whose behalf funds are deposited or withdrawn from this account.

(6) If a patient's or resident's personal funds are deposited in an interest bearing account, the accrued interest shall, unless otherwise specified by law, be prorated in accordance with the amounts attributable to each patient or resident and recorded on the patient's or resident's account.

(7) Upon the request of the patient or resident or the patient's or resident's guardian or conservator, the nursing home or boarding care home shall return all or any part of the patient's or resident's funds given to the nursing home or boarding care home for safekeeping, including interest, if any, accrued from deposits. The nursing home or boarding care home shall develop a policy specifying the period of time for each day of the week that funds can be withdrawn. Funds kept outside of the facility shall be returned within three banking days.

d. Discharge of patient or resident. Upon discharge of a patient or resident, unless the patient's or resident's bed is being held for anticipated readmission, all funds of that patient or resident shall be returned to the patient or resident or to an authorized individual, with a written accounting, in exchange for a signed receipt. Funds which are maintained outside of the nursing home or boarding care home shall be returned within three banking days.

e. Death of a patient or resident. Upon the death of a patient or resident, the nursing home or boarding care home shall provide a complete accounting of that patient's or resident's funds and shall return the funds to the appropriate individuals in accordance with state law.

f. Change of ownership. Prior to a change of ownership of a nursing home or boarding care home, a written verification by a public accountant of all patients' and residents' funds shall be provided to the new licensee in exchange for a signed receipt.

9. ~~(9)~~ Policy records. All policies and procedures adopted by the home shall be placed on file and be made readily accessible to the personnel.

10. ~~(10)~~ Unusual occurrences. Any occurrence of food poisoning or reportable disease shall be reported immediately to the department.

11. ~~(11)~~ Employees' personnel records. A current personnel record shall be maintained for each employee and placed on file in a locked cabinet in the office of the administrator, person in charge or the business office. These records shall be available to representatives of the department and shall contain the following information:

a. ~~(a)~~ Person's name, address, telephone number, age and birth date; sex, marital status, Minnesota license or registration number, if applicable; name, address and telephone number of person to be called in case of emergency; social security number; and similar identifying data.

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b. ~~(bb)~~ Resume of individual's training, experience and previous employment; recommendations and references from previous employers.

c. ~~(cc)~~ Dates and results of any pre-employment physical examination and of any subsequent physical examinations.[2]

d. ~~(dd)~~ Date of employment in home; type of position currently held in home; hours of work; attendance and salary records.

e. ~~(ee)~~ The record of all illnesses and accidents.

f. ~~(ff)~~ A listing of all institutes or training courses attended.

g. ~~(gg)~~ At least annual evaluations concerning employee's work performance.

h. ~~(hh)~~ Date of resignation or discharge and reason for leaving.

7 MCAR § 1.049 ~~MHD 49~~ Medical and dental services.

C. ~~(c)~~ Physicians' examinations and orders.

1. ~~(1)~~ Each patient or resident shall have an admission medical history and complete physical examination performed and recorded by a physician within five (5) days prior to or within 72 hours after admission. The medical record shall include: the report of the admission history and physical examination; the admitting diagnosis and report of subsequent physical examinations; ~~a report of a standard Mantoux tuberculin test or, if the Mantoux test is positive or contraindicated, a chest X-ray within three (3) months in advance of admission and as indicated thereafter;~~ a report of a negative full-sized chest X-ray taken within 45 days prior to admission; if chest X-ray positive, documentation from a physician of freedom from active tuberculosis disease, or documentation from a physician of completion of a preventive tuberculosis therapy; reports of appropriate laboratory examinations; general medical condition including disabilities and limitations; instructions relative to the patient's or resident's total program of care; written orders for all medications with stop dates, treatments, special diets and for extent or restriction of activity; physician's orders and progress notes; and condition on discharge or transfer, or cause of death.

2. ~~(2)~~ Each nursing home patient shall be examined by a physician at least every 6 months and each boarding care home resident at least annually or more often if indicated by the clinical condition. A progress note shall be recorded in the patient's or resident's record at the time of each examination.

3. ~~(3)~~ If orders for the immediate care of a patient or resident are not available at the time of admission, the emergency physician shall write temporary orders which are effective for a maximum of 72 hours.

7 MCAR § 1.052 A.1. ~~MHD 52(a)(1)~~ Patient and resident units.

a. ~~(1)~~ A comfortable bed at least 36 inches wide, good springs and a clean, firm, comfortable mattress and mattress pad. At least one clean, comfortable pillow with extra pillows available to meet the patient's needs. Clean, lightweight blankets and bed linen in good condition and of the proper size shall be kept on hand for use at all times. Clean sheets and pillow cases shall be furnished at least once a week. Each bed shall have a washable bedspread. A moisture-proof mattress cover or rubber or plastic sheeting shall be provided for mattresses of all bed patients and for other beds as necessary. Rollaway type beds, cots, or folding beds ~~or double beds~~ shall not be used.

b. The nursing home and boarding care home shall develop a written policy regarding the use of double beds.

7 MCAR § 1.053 ~~MHD 53~~ Medications.

F. ~~(f)~~ Disposition of medications.

1. If authorized by the attending physician or the physician in charge, medications belonging to patients shall be given to them when discharged or transferred. This shall be recorded on the patient's chart. Unused portions of controlled substances shall be handled by contacting the ~~Bureau of Narcotics and Dangerous Drugs. The Bureau will furnish the necessary instructions and appropriate forms.~~ Minnesota Board of Pharmacy who shall furnish the necessary instructions and forms, a copy of which shall be kept on file in the home for two years. Any other unused portions of prescription drugs remaining in the nursing home after the death or discharge of the patient for whom they were prescribed, or any prescriptions discontinued permanently, shall be destroyed by the supervising nurse in the nursing home by flushing them into the sewer system and removing and destroying the labels from the containers~~.~~, or handled in accordance with F.2., below. A notation of any such destruction giving date, quantity, name of medication and prescription number shall be recorded on the patient's chart. Such destruction shall be witnessed and the notation signed by both persons.

2. Drugs and prescribed medications, other than controlled substances, used in nursing homes may be returned to the dispensing pharmacy in accordance with the provisions of the Minnesota Board of Pharmacy rule, 7 MCAR § 8.032 B.

7 MCAR § 1.055 ~~MHD 55~~ Dietary service and sanitation.

U. ~~(u)~~ Dishwashing. The dishwashing operation shall provide proper separation in the handling of soiled and clean dishes and utensils, and shall conform with the following procedures for washing, rinsing, sanitizing and drying. ~~Chemical disinfection is not acceptable.~~

1. ~~(1)~~ Machine washing of dishes and utensils.

a. Hot water sanitizing. The dishwashing machine shall be operated in accordance with the manufacturer's instructions which shall be posted nearby; see MHD 67(clii). The flow pressure shall be maintained between 15 and 25 pounds per square inch (psi) at the dishwasher. The temperatures of the water shall be maintained at 140°-160°F. for the washing cycle, and at 170°F. for the rinsing and sanitizing cycle, both temperatures measured at tray level. If the same person handles both

[2]Annual physical examinations are recommended.

soiled and clean dishes, he shall wash his hands between operations. Dishes and utensils shall be air dried.

b. Chemical sanitizing.

(1) Equipment.

(a) Dishwashing machines using chemicals for sanitizing shall bear labeling indicating that the machine has been approved by the National Sanitation Foundation.

(b) Each dishwashing machine shall be equipped with an audible signaling device which indicates when the detergent supply or chemical sanitizing supply is empty. The signaling device shall be maintained in an operating condition.

(c) The pressure of final rinse water supplies to spray-type dishwashing machines shall not be less than 15 or more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A pressure gauge shall be provided immediately upstream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(d) The clean dish counter shall provide space for at least 4 racks of clean and sanitized dishes and utensils.

(2) Operation.

(a) The dishwashing machines shall be operated in accordance with the manufacturer's instructions which shall be posted nearby.

(b) The temperature of the wash water shall not be less than 140°F. (60°C.)

(c) Chemicals added for sanitation purposes shall be automatically dispensed in accordance with the manufacturer's specifications for time and concentration.

(d) The chemical sanitizing rinse water temperature shall not be less than 75°F. (24°C.) nor less than the temperature specified by the chemical manufacturer.

(e) All chemical sanitizers used in the dishwashing machines shall bear labeling indicating that the chemical sanitizers are registered by the Environmental Protection Agency and shall contain specific instructions for use.

(f) A test kit or other device that accurately measures the parts per million concentration of the sanitizing solution shall be available and used in accordance with this section.

(i) The concentration level shall be tested in accordance with the manufacturer's instruction each time the machine is used.

(ii) The results of the testing shall be recorded in a written log which specifies the result of the test and shall be signed by the individual making the test. The log shall include the name of the chemical used and the manufacturer's recommended concentration of the chemical. This written log shall be maintained for the previous 3 months.

(g) If the same person handles both soiled and clean dishes, he shall wash his hands between operations.

(h) Dishes and utensils shall be air dried.

(i) The dishwashing machine shall be thoroughly cleaned at least once a day in accordance with the manufacturer's recommendation.

2. ~~(2)~~ Hand washing of pots and pans. A three-compartment scullery sink (see MHD 65 (b2aa3)) shall be utilized as follows for a complete washing cycle by hand of pots and pans. The first comparment is for soaking and washing, the second compartment is for rinsing, and the third compartment for sanitizing. Sanitizing is accomplished by complete immersion for at least two (2) minutes in 170°F. water. A unit heater capable of maintaining the water in the sanitizing compartment at 170°F. shall be provided, including a long handled wire basket for the removal of the sanitized items. The temperature shall be monitored with a thermometer. If the mechanical dishwasher is used for sanitizing of pots and pans, a sanitizing comparmtent is not required. Only air drying is permitted.

7 MCAR § 1.057 ~~MHD 57~~ Schedule of fines for uncorrected deficiencies.
[Applies to both nursing homes and boarding care homes.]

A. ~~(a)~~ A $50 penalty assessment will be issued under the provisions of Minn. Stat. § 144.653, subd. 6 (1974) for noncompliance with correction orders relating to the sections of these rules listed below.

MHD 44 (o); (p); (q); (s); (t); (u)
MHD 45 (a) (3); (f); (h)(1); (h)(2)(aa); (h)(2)(ff); (h)(4)
MHD 46 (a); (b); (j); (k)
MHD 47 (c); (e)
MHD 48 (a)(4); (a)(5); (a)(6); (a)(7); (a)(9); (a)(11)
MHD 50 (a); (j)
MHD 52 (a)(2); (a)(3); (a)(4); (a)(9); (d); (e)
MHD 54 (a)(7); (b)(5)
MHD 55 (i)
MHD 56 (f); (h)
MHD 64 (a)(22); (b)(15)

B. ~~(b)~~ A $250 penalty assessment will be issued under the provisions of Minn. Stat. § 144.653, subd. 6 (1974) for noncompliance with correction orders relating to all other sections of these regulations not specifically enumerated in A. ~~(a)~~ above or C.

C. Nursing homes.

1. A $50 penalty assessment will be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

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a. 7 MCAR § 1.048 A.4.

b. 7 MCAR § 1.048 A.8.a.

c. 7 MCAR § 1.048 A.8.b.(2)

d. 7 MCAR § 1.048 A.8.c.(3)

e. 7 MCAR § 1.048 A.8.c.(5)

f. 7 MCAR § 1.048 A.8.c.(6)

g. 7 MCAR § 1.048 A.8.d.

h. 7 MCAR § 1.048 A.8.e.

i. 7 MCAR § 1.048 A.8.f.

j. 7 MCAR § 1.052 A.1.b.

k. 7 MCAR § 1.053 F.2.

l. 7 MCAR § 1.055 U.1.b.(1)(d)

m. 7 MCAR § 1.064 A.3.f.(1)(a)

2. A $150 penalty assessment will be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.046 L.2.b.

b. 7 MCAR § 1.046 L.2.c.

c. 7 MCAR § 1.046 L.2.d.

d. 7 MCAR § 1.046 L.2.e.

e. 7 MCAR § 1.046 L.2.f.

f. 7 MCAR § 1.047 A.

g. 7 MCAR § 1.048 A.8.b.(1)

h. 7 MCAR § 1.048 A.8.c.(1)

i. 7 MCAR § 1.048 A.8.c.(2)

j. 7 MCAR § 1.048 A.8.c.(4)(a)

k. 7 MCAR § 1.048 A.8.c.(4)(b)

l. 7 MCAR § 1.048 A.8.c.(4)(c)

m. 7 MCAR § 1.048 A.8.c.(7)

n. 7 MCAR § 1.055 U.1.b.(1)(a)

o. 7 MCAR § 1.055 U.1.b.(1)(b)

p. 7 MCAR § 1.055 U.1.b.(1)(c)

q. 7 MCAR § 1.055 U.1.b.(2)(a)

r. 7 MCAR § 1.055 U.1.b.(2)(b)

s. 7 MCAR § 1.055 U.1.b.(2)(c)

t. 7 MCAR § 1.055 U.1.b.(2)(d)

u. 7 MCAR § 1.055 U.1.b.(2)(e)

v. 7 MCAR § 1.055 U.1.b.(2)(f)

w. 7 MCAR § 1.055 U.1.b.(2)(g)

x. 7 MCAR § 1.055 U.1.b.(2)(h)

y. 7 MCAR § 1.055 U.1.b.(2)(i)

3. A $250 penalty assessment shall be assessed on a daily basis to a nursing home for non-compliance with correction orders relating to the following rules:

a. 7 MCAR § 1.046 L.2.a.

b. 7 MCAR § 1.049 C.1.

c. 7 MCAR § 1.064 A.3.f.(1)(b)

7 MCAR § 1.058 Allowable time periods for correction.

A. Allowable time periods for correction. The allowable time periods for complying with a correction order issued by the department shall be as follows:

1. 7 MCAR § 1.046.	
a. L.2.a.	30 days
b. L.2.b.	14 days
c. L.2.c.	14 days
d. L.2.d.	14 days
e. L.2.e.	14 days
f. L.2.f.	14 days
2. 7 MCAR § 1.047 A.	14 days
3. 7 MCAR § 1.048.	
a. A.4.	14 days
b. A.8.a.	30 days
c. A.8.b.	14 days
d. A.8.c.(1)	30 days
e. A.8.c.(2)	30 days
f. A.8.c.(3)	30 days
g. A.8.c.(4)(a)	14 days
h. A.8.c.(4)(b)	30 days
i. A.8.c.(4)(c)	30 days
j. A.8.c.(5)	30 days
k. A.8.c.(6)	30 days
l. A.8.c.(7)	14 days
m. A.8.d.	14 days
n. A.8.e.	14 days
o. A.8.f.	30 days
4. 7 MCAR § 1.049 C.1.	14 days
5. 7 MCAR § 1.052 A.1.b.	30 days
6. 7 MCAR § 1.053 F.2.	30 days
7. 7 MCAR § 1.055.	
a. U.1.b.(1)(a)	60 days
b. U.1.b.(1)(b)	30 days
c. U.1.b.(1)(c)	14 days
d. U.1.b.(1)(d)	60 days
e. U.1.b.(2)(a)	14 days

f. U.1.b.(2)(b)	14 days
g. U.1.b.(2)(c)	14 days
h. U.1.b.(2)(d)	14 days
i. U.1.b.(2)(e)	14 days
j. U.1.b.(2)(f)	14 days
k. U.1.b.(2)(g)	14 days
l. U.1.b.(2)(h)	14 days
m. U.1.b.(2)(i)	14 days
8. 7 MCAR § 1.064.	
a. A.3.f.(1)(a)	30 days
b. A.3.f.(1)(b)	14 days

B. Extension of the allowable time period for correction.

1. Request for extension. The administrator of the nursing home may request an extension of the allowable time for correction for those rules specified in A., above. The request for extension of the allowable period of time for correction shall be received by the department prior to the expiration of the time period cited in the correction order. The failure to submit a request within that time period shall result in a denial of the request.

2. Contents of request.

a. All requests for an extension of the allowable time period for correction shall contain the following information:

(1) The identification of the rule or rules for which the correction order was issued;

(2) The date the correction order was received;

(3) The allowable time period for correction;

(4) The reasons for requesting an extension of the allowable time period for correction which shall specify, in detail, the steps that have been taken by the nursing home to attain compliance;

(5) The length of additional time required to attain compliance with the correction order; and

(6) Such other relevant information which the department shall determine is necessary to evaluate the request for the extension of time.

b. If the request for an extension is made orally, the administrator shall mail, within 24 hours, a written confirmation which contains the information specified under 2.a., above.

3. Criteria for evaluation.

a. A request for an extension of the allowable period of time shall be granted if the department determines that:

(1) Continued non-compliance with the rule for the length of the extension will not jeopardize the health, treatment, comfort, safety or well-being of the patients; and

(2) The nursing home:

(a) Has entered into a contract to obtain the materials, labor, personnel, or other items necessary to obtain compliance with the correction order, but the supplies, contractor or individual has failed to perform or is unable to perform within the time period specified and the inability of the nursing home to comply with the correction order is due solely to that failure; or

(b) Has otherwise made a diligent good faith effort to comply with the correction order since its receipt.

b. The administrator shall be notified, in writing, of the department's decision. If an extension of time is granted, the notification shall specify the additional time allowed for correction.

4. Renewal.

a. Any request for the renewal of an extension of the allowable time period for correction shall be made in accordance with B.1. and 2., above.

b. Approval for the renewal of an extension of the allowable time period for correction shall be granted if the department determines that the nursing home continues to meet the criteria contained in B.3., above.

5. Denial. The department shall deny any request for an extension of the allowable time period for correction if it determines that the criteria specified in B.3., above, are not met. The denial shall be in writing and shall list the reasons for the denial.

7 MCAR § 1.064 A.3.f. ~~MHD 64(a)(3)(ff)~~ Bedroom doors.

(1) ~~(ff1)~~ Existing and new. ~~There shall be no locks on patient room doors.~~

(a) The nursing home shall develop a written policy regarding the use of locks on patient bedroom doors. The policy shall address whether or not doors can be locked while the patient is in the room.

(b) Any locks installed on patient bedroom doors shall be so arranged that they can be locked only from the corridor side. All such locks shall permit exit from the room by a simple operation without the use of a key. All locks shall be openable with a master key which is located at each nursing station.

KEY: RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language. PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material."

Department of Health
Health Systems Division

Notice of Public Hearing to Solicit Outside Opinion on Certain Rules Relating to the Licensing of Nursing Homes

Notice is hereby given that a public hearing will be held in Room 105 of the Minnesota Department of Health, 717 Delaware Street S.E., Minneapolis, Minnesota on April 2, 1980 at 9:30 a.m. and continuing until all persons have had an opportunity to be heard. The purpose of the hearing will be to obtain public comment concerning certain nursing home rules.

The Legislative Commission to Review Administrative Rules has requested that the Department of Health hold a public hearing to solicit outside opinion regarding certain provisions contained in the department's rules for the licensing and regulation of nursing homes. Testimony received at this hearing will assist the department in determining whether or to what extent these rules should be amended. The rules which shall be reviewed during this meeting are as follows:

MHD 50(e)(1)—Nursing staff.

The nursing home shall have on duty at all times a sufficient number of qualified nursing personnel which includes registered nurses, licensed practical nurses, nurses aides and orderlies to meet the needs of the patients on all nurses' stations, on all floors and in all buildings if more than one building is involved. This includes relief duty, weekends and vacation replacements. On and after July 1, 1973, a minimum of two (2) hours of nursing personnel per patient per 24 hours plus additional qualified nursing staff commensurate with the needs of the patients shall be provided.

MHD 54(a)(5)—Laundering of linen.

Linen shall be washed in commercial-type washers. The water temperature inside the washers shall be at least 160°F. during the main washing and rinsing cycles for a total time of at least 30 minutes, excluding time for filling and draining. Contaminated linen shall be thoroughly preflushed separately before being introduced to the main washing and rinsing process.

MHD 64(a)(1)(aa)—Bedroom capacities.

New construction: At least 5% of the rooms shall be designed for single person occupancy (1 bed), and shall have private toilet rooms. At least 75% of the beds shall be located in rooms designed for one or two beds. No room shall have more than four (4) beds.

All persons will be afforded the opportunity to be heard through the presentation of oral and written statements. Evidence submitted for consideration should be pertinent to the matter at hand. Written material received by the Department of Health will become part of the hearing record. For further information, contact Michael Tripple at the above address, or by phone at (612) 296-5418.

February 11, 1980

George R. Pettersen, M.D.
Commissioner of Health

Housing Finance Agency

Proposed Amendments to Rules Relating to the Home Improvement Grant Program, the Definition of Developmentally Disabled, and American Indian Housing Programs

Notice of Hearing

Notice is hereby given that a public hearing will be held in the above entitled matter in the Capitol Square Building, Conference Room A, 550 Cedar Street, St. Paul, Minnesota, 55101, on Friday, March 28, 1980, commencing at 9:00 a.m. and continuing until all interested or affected persons have had an opportunity to participate.

All representatives of associations or other interested groups and all interested or affected persons will have an opportunity to be heard concerning the adoption of the proposed rules captioned above by submitting either oral or written data, statements or arguments. Statements or briefs may be submitted by mail without personally appearing at the hearing to Natalie Gaull, Hearing Examiner, at Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, telephone (612) 296-8114. For those wishing to submit written statements or exhibits, it is requested that at least three (3) copies be furnished. In addition, it is suggested to save time and avoid duplication, that those persons, organizations or associations having a common viewpoint or interest in these proceedings join together where possible and present a single statement on behalf of such interests. All such statements will be entered into and become part of the record. The conduct of the hearing will be governed by the rules of the Office of Hearing Examiners.

Notice is hereby given that 25 days prior to the hearing a Statement of Need and Reasonableness will be available for review at the agency and at the Office of Hearing Examiners. This Statement of Need and Reasonableness will include a summary of all of the evidence which will be presented by the agency at the hearing, justifying both the need for and the reasonableness of the proposed rules. Copies of the Statement of Need and Reasonableness may be obtained from the Office of Hearing Examiners at a minimal charge.

After the public hearing, written material may be submitted to the hearing examiner and recorded in the hearing record for five working days, or for a longer period not to exceed 20 calendar days if so ordered by the hearing examiner.

Transportation Company (with Attorneys at 4200 IDS Center, 80 South 8th Street, Minneapolis, Minnesota) has filed a petition with the Commissioner of Transportation pursuant to Minn. Stat. §§ 219.741, and 218.041, subd. 3 (10) to retire and remove Track No. 9, 550 feet long including Turnout, and Track No.15, 550 feet long including Turnout, located at St. Paul, Minnesota.

Any person may file a written objection to the proposed action by means of a letter addressed to the Commissioner of Transportation, Transportation Building, Saint Paul, Minnesota 55155, not later than the date specified below. An objection must be received on or before April 7, 1980. The objection should state specifically how the objector's interest will be adversely affected by the proposed action.

The petition recites among other matters that:

"The subject track is no longer needed for rail transportation service, constitutes a continuing and burdensome maintenance expense, and is an unnecessary safety hazard. The track is not used at the present time, and there is no present prospect that the track will be needed in the future. The only shipper, patron or member of the public who might have any interest in the retention of the tracks or facilities, or who has used the same to any substantial degree within the past several years, is West Publishing Company . . . (50 W. Kellogg Boulevard, P.O. Box 3526, St. Paul, Minnesota 55102)."

Upon receipt of a written objection, the commissioner will, with respect to the named petitioner, set the matter down for hearing. If no objections are received, the commissioner may grant the relief sought by the petitioner.

If this matter is set for hearing, any person who desires to become a party to this matter must submit a timely Petition to Intervene to the hearing examiner pursuant to 9 MCAR § 2.210, showing how the person's legal rights, duties and privileges may be determined or affected by the decision in this case. The petition must also set forth the grounds and purposes for which intervention is sought. All parties have the right to be represented by legal counsel or any other representative of their choice. In the event the objecting party does not do so, or otherwise does not participate in the hearing, the statements contained in the application filed may be taken as true.

March 10, 1980

Richard P. Braun
Commissioner

Errata

At *State Register*, Vol. 4, Number 34, p. 1321, February 25, 1980 (Department of Health, Proposed Amendments to Rules for Construction, Equipment, Maintenance, Operation and Licensing of Nursing Homes and Boarding Care Homes), please make the following correction:

7 MCAR § 1.048 A.8.c.(5): Change "in excess of $10.000" to read "in excess of $100.00."