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Minnesota Department of Health

Report on All Minnesota Department of Health Rules

August 1, 2001



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— Minn. Stat. 14.3961

— 2000 Minn. Laws Chap. 469
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Report on All Minnesota Department of Health Rules

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Report on All Minnesota Department of Health Rules
August 1, 2001
Made to the Governor and the Legislature
As required by Minnesota Statutes, section 14.3691

Cost of preparing this report. In compliance with Minnesota Statutes, section 3.197, the cost of preparing this report is approximately \$2,000.00.

Executive Summary

Requirement to report on all MDH rules. Minnesota Statutes, section 14.3961, states in pertinent part:

“An entity whose rules are scheduled for review under this section must report to the governor and the appropriate committees of the legislature by August 1

The report must:

- (1) list any rules that the entity recommends for repeal;
- (2) list and briefly describe the rationale for rules that the entity believes should remain in effect; and
- (3) suggest any changes in rules that would improve the agency's ability to meet the regulatory objectives prescribed by the legislature, while reducing any unnecessary burdens on regulated parties. ...”

Rules recommended for repeal. This is a list of rules we recommend for repeal. The reasons for our recommendations are discussed in the body of this report:

- Part 4620.1800 – Clean Indoor Air; Formaldehyde
- Parts 4620.3900 to 4620.4900 – Clean Indoor Air; Enclosed Arenas
- Chapter 4647 - Health Care Equipment Loan Program
- Chapter 4667 – Home Care Providers; Fees
- Part 4735.0200 – Licensure Fees
- Some portions of Chapter 9000 – Office of Mental Health Practice

Rules that should remain in effect. We recommend that the large majority of MDH rules remain in effect. The rules, along with the rationale for our recommendations, are listed in the body of this report.

Suggested rule changes. We suggest a number of improvements to MDH rules. These changes are discussed in the body of this report.

Organization of this report. This report is organized by MDH division with a paragraph or two discussing each rules chapter or section.

Report

Requirement to report on all MDH rules. Minnesota Statutes, section 14.3961, subdivisions 1 and 2, state in pertinent part:

“14.3691 RULE REVIEW AND LEGISLATIVE OVERSIGHT.

Subdivision 1. **Reports.** An entity whose rules are scheduled for review under this section must report to the governor and the appropriate committees of the legislature by August 1 of the year before the legislative session in which the entity's rules are scheduled for review. The speaker of the house of representatives and the senate committee on rules and administration shall designate the appropriate committees to receive these reports. The report must: (1) list any rules that the entity recommends for repeal; (2) list and briefly describe the rationale for rules that the entity believes should remain in effect; and (3) suggest any changes in rules that would improve the agency's ability to meet the regulatory objectives prescribed by the legislature, while reducing any unnecessary burdens on regulated parties. Any costs of preparing this report must be absorbed within funds otherwise appropriated to the entity.

Subd. 2. **Schedule.** (a) Rules of the ... health department will be reviewed before and during the legislative session in 2002. ...”

Environmental Health Division

Parts 4620.0050 to 4620.1450 – Clean Indoor Air; Tobacco Smoke

Minnesota Rules, parts 4620.0050 to 4620.1450, protect the public health by preventing exposure to tobacco smoke. MDH is currently proposing changes to these rules to include updates to outdated statutory citations, clarifications requested by local agencies that enforce the Minnesota Clean Indoor Air Act (MCIAA), and increased protection of nonsmokers. MDH's proposed changes to the MCIAA rules are currently under review by the Governor's Office and will be published for public comment and hearing once they are approved by the Governor's Office. We recommend these rules remain in effect as amended.

Part 4620.1800 – Clean Indoor Air; Formaldehyde

Minnesota Rules, part 4620.1800, protects the public health by preventing exposure to formaldehyde. In the 20 years since these requirements were first enacted, the industry has developed voluntary product standards that negate the need for the less restrictive Minnesota statute and rule. In addition, the federal government, through the Department of Housing and Urban Development, has promulgated rules for manufactured home construction and safety standards that preempt the state rules. The Code of Federal Regulations addresses formaldehyde emission controls for certain wood products that are lower than the state limits. (Code of Federal Regulations, title 24, chapter XX, part 3280, subpart D, section 3280.308.) MDH recommended repeal of the statutory authority (Minnesota Statutes, section 144.495) and of the rules during the

2001 legislative session; however, this repeal language did not pass. We still recommend that this rule be repealed.

Parts 4620.3000 to 4620.3724 – Clean Indoor Air; Asbestos

Minnesota Rules, parts 4620.3000 to 4620.3724, reduce public exposure from asbestos by setting work practice standards to abate asbestos hazards. State regulation of the asbestos abatement industry reduces exposure of citizens to harmful asbestos fibers. These rules also cover the credentialing of asbestos contractors and other professionals and specify the training, experience, and education necessary to perform their duties in a manner protective of public health. Minor amendments of these rules became effective in June 2001, and we have no suggestions for further changes at this time. We recommend these rules remain in effect.

Parts 4620.3900 to 4620.4900 – Clean Indoor Air; Enclosed Arenas

Minnesota Rules, parts 4620.3900 to 4620.4900, have not been updated since 1973 and they are obsolete. Many arenas are using new technology, such as electric ice resurfacers, which do not release carbon monoxide or nitrogen dioxide. If high levels of carbon monoxide or nitrogen dioxide are released from internal combustion engine-powered machines, it tends to be an isolated event. Routine inspections rarely find violations of the air standards. With so few ice arenas, just over 200 in Minnesota, the cost of enforcement per arena is relatively high. MDH recommended repeal of the statute (Minnesota Statute, section 144.1222, subdivision 3) and rules during the 2001 legislative session and this repeal language did not pass. We still recommend that these rules be repealed.

Chapter 4625 – Lodging Establishments

Minnesota Rules, chapter 4625, protects the public health of Minnesota citizens and tourists by ensuring that our lodging establishments provide a safe drinking water supply and sewage disposal system. The rules also address possible health issues associated with ice dispensing, insects and rodents, disposal of fish waste, and general maintenance and cleaning. We plan to review these rules in the next two to four years to identify areas to be updated and any obsolete or unnecessarily burdensome requirements. We recommend these rules remain in effect.

Chapter 4626 – Food Code; Food Managers

Minnesota Rules, chapter 4626, protects the public health by emphasizing the reduction of food handling procedures which have been shown to contribute to food borne illness in food and beverage establishments. The principles of hazard analysis of critical control points are used to reduce the potential for food borne illness.

The code is modeled after the 1997 U.S. Food and Drug Administration Food Code and is jointly administered by the Minnesota Departments of Health and Agriculture. The most recent code was adopted in September 1998 and, as part of the review process, over 75 rule parts deemed to be obsolete or unnecessarily burdensome were repealed. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4630 – Mobile Home Parks and Camps

Minnesota Rules, chapter 4630, ensures the health and safety of persons living in or using these facilities. Occupants, including tourists and children, live in a high-density environment and are potentially subject to various health and safety hazards. The rules cover water supplies, sewage treatment, spacing for fire protection, handling and disposal of garbage and refuse, insect and rodent harborage and infestation control, plumbing, and other potential hazards to users.

Parts 4630.4800 to 4630.6550, covered health and safety in migrant labor camps. These rules were considered inadequate by MDH to protect health and safety in the camps. MDH felt that existing lodging, mobile home park and other housing rules would provide a much higher degree of protection. Therefore, these parts will be repealed, effective January 1, 2002. We plan to review the remaining parts of the rules in the next one to three years to identify areas to be updated and any obsolete or unnecessarily burdensome requirements. Other than the repealed parts of the rules, we recommend these rules remain in effect.

Chapter 4635 – Roller Towels

These rules were repealed, effective April 26, 2001.

Chapter 4695 – Environmental Health Specialists/Sanitarians

Minnesota Rules, chapter 4695, covers the qualifications and registration of the environmental health specialist/sanitarian profession. They ensure that environmental health practitioners in various environmental health fields are qualified by reason of training, experience, and education to perform their duties in a professional manner. There are currently about 300 persons so registered and include employees of municipal, county, and state jurisdictions as well as private industry. We have no suggestions for changes at this time. In order to maintain a high level of competence in these fields, we recommend these rules remain in effect.

Chapter 4715 – Minnesota Plumbing Code

Minnesota Rules, chapter 4715, protects the public health by specifying the installation requirements necessary to install and maintain plumbing systems in a safe and sanitary condition. These rules also cover the credentialing of plumbers and water conditioner contractors and specify the training, experience, and education necessary to perform their duties in a manner protective of public health. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4717.0100 to 4717.3975 – Public Swimming Pools

Minnesota Rules, parts 4717.0100 to 4717.3975, provide minimum standards for construction, operation, and maintenance of pools and spas used by the public. The rules set the requirements for health and safety protection of public pool and spa users on items including: pool, spa, and deck structure; filtration, water treatment, and safety equipment; operator training; and operation and maintenance. The rules also require pool and spa plan review and approval by MDH prior to

construction, to ensure that proposals that would not comply with this code are corrected before installation. There are numerous injury, drowning, and disease transmission risks associated with public pools and spas. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4717.4000 to 4717.6900 – Marine Toilets

Minnesota Rules, parts 4717.4000 to 4717.6900, provide public health protection and protection of public waters by regulating the construction of on-land disposal facilities and the transfer of wastes from marine toilets equipped with retention services. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4717.7000 to 4717.7050 – Variances

Minnesota Rules, parts 4717.7000 to 4717.7050, provide the criteria and conditions necessary to vary environmental health rule requirements, and the process for appealing when a variance has been denied, revoked, or not renewed by the Commissioner. These rules meet or exceed the standards recently established by the 2001 Legislature in Minnesota Statutes, sections 14.055 and 14.056. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4717.7100 to 4717.7800 – Health Risk Limits

Minnesota Rules, parts 4717.7100 to 4717.7800, establish limits for substances found to degrade Minnesota groundwater. The Health Risk Limits (HRLs) are health-based exposure limits that are routinely used as benchmarks by state and local groundwater protection programs in permitting, remediation and clean-up activities, environmental review, and case-by-case health risk assessments. Currently, MDH is conducting background research for an upcoming revision of the HRL rules. Under consideration are revisions of existing HRLs to reflect new health risk data and the addition of new HRLs for chemicals not in rule. Current risk assessment methods and policies used to derive HRLs are also being examined to determine whether they adequately protect children. We recommend these rules remain in effect.

Chapter 4720 – Public Water Supplies

Minnesota Rules, chapter 4720, sets a wide variety of public health standards and requirements related to protecting public water supplies. The rules require approval of engineering plans and specification by MDH before the installation, alteration, or extension of a water system may begin. This is a preventive activity that helps ensure a safe drinking water supply through proper construction of drinking water facilities. The rules require all municipal water systems to maintain a specified concentration of fluoride in the drinking water, which has been proven to prevent dental cavities. The rules require public water systems to monitor for contaminants in their drinking water, set standards for allowable limits of contaminants in drinking water, and prescribe treatment techniques and actions to take in the event contamination is detected. The rules also set sanitary procedures for those who distribute drinking water by tank truck.

These rules provide public health protection during natural and other disasters when public water supplies or private water wells are unable to be used. The rules set requirements for the protection of groundwater sources used by public water supplies, including the development of a wellhead protection plan. This major preventive activity ensures a safe drinking water supply through protection of the source water for the well. The Drinking Water Revolving Fund sets requirements for the provision of financial assistance to eligible public drinking water suppliers for construction of facilities that ensure safe and adequate drinking water. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4725 – Minnesota Well Code

Minnesota Rules, chapter 4725, establishes requirements for the location, construction, and ultimate closure (sealing) of wells and borings, to protect the health of people drinking water from wells (approximately 80% of Minnesotans), and to preserve the quality of the state's significant groundwater resources. The rules establish credentialing requirements for well contractors and equipment and permit and notification requirements for the construction and sealing of wells and borings.

MDH last revised location and construction requirements in 1993, and is in the process of holding informal discussions with the well drilling industry and other interested parties in preparation for a limited rules revision in 2003. We have no recommendations for further changes and recommend these rules remain in effect.

Chapter 4727 – Explorers and Exploratory Borings

Minnesota Rules, chapter 4727, requires licensing of persons (explorers) doing exploratory drilling, and the regulation of drilling (exploratory boring) done to prospect or explore for oil, natural gas, kaolin clay, or metallic minerals such as gold, copper, or uranium. Legislative concerns for uranium exploration led to the eventual adoption of these rules in 1981. The rules establish minimum licensing requirements for explorers, require notification prior to drilling, establish reporting requirements, and set standards for filling or "sealing" of the drill holes when they are no longer needed. The purposes of the rules are to protect the health and safety of the public and the explorers, and to preserve Minnesota's groundwater resource which serves as a source of drinking water for 80% of the public.

The rules are currently under review due to statutory amendments to Minnesota Statutes, chapter 103I, recommendations from the regulated community, and changes in technology and construction that have occurred in the 20 years since the rules were adopted. We recommend that the current rules remain in effect until amended.

Chapter 4730 – Ionizing Radiation

Minnesota Rules, chapter 4730, was adopted to protect public health and to control hazards from sources of radiation and the handling, storage, use, and disposal of radioisotopes and fissionable materials. The rules apply to all who own, possess or use sources of radiation, larger than exempt quantities, in Minnesota. The radiation sources are generally used in industry, healing

arts, research, and education, except for radioactive materials that are regulated by the U.S. Nuclear Regulatory Commission (NRC), including nuclear power plants. Due to the potential hazards from sources of radiation, we recommend these rules remain in effect.

MDH is currently pursuing an agreement on behalf of the Legislature and Governor with the NRC for the assumption of the regulation of the byproduct, source, and certain special nuclear materials. Draft rules, chapter 4731, are being prepared for the assumption of regulation of the additional radioactive materials. The new rule will include all of the current chapter 4730, which will be repealed in its entirety.

Chapter 4761 – Residential Lead Abatement

Minnesota Rules, chapter 4761, was adopted to protect the public health, in particular the health of young children and pregnant women, from the hazards of lead paint and other household materials containing lead. The rules reduce exposure from lead by setting work practice standards to abate lead hazards. These rules also cover the credentialing of contractors and other professionals and specify the training, experience, and education necessary to perform their duties in a manner protective of public health.

Amendments to the lead statute were passed during the 2001 legislative session. These statutory changes will necessitate making amendments to the lead rule within the next year. We recommend these rules remain in effect until amended.

Chapter 9400 – Water Treatment Certification

Minnesota Rules, chapter 9400, establishes requirements for individuals to be certified as water or wastewater treatment operators, and for the classification of drinking water systems and wastewater facilities. These rules are enforced by MDH (drinking water) and MPCA (wastewater). The competency of the operator in charge of a drinking water system is critical for the protection of public health and the maintenance of a safe, optimally run, and reliable facility. We have no suggestions for changes at this time and recommend these rules remain in effect.

Center for Health Statistics

Chapter 4601 – Vital Statistics

Minnesota Rules, chapter 4601, was promulgated to provide direction in the collection, filing, and registering of vital statistics information by state and local registrars, physicians, morticians, and others. These rules serve as a mechanism by which the State Registrar, under delegated authority by the Commissioner of Health, protects Minnesota's vital statistics from fraudulent use of birth or death records. The rules were recently updated to reflect changes required due to implementation of a centrally managed electronic birth and death records system for Minnesota. We have no suggestions for changes at this time and recommend these rules remain in effect.

Health Policy and Systems Compliance Division

Chapter 4647 - Health Care Equipment Loan Program

Minnesota Rules, chapter 4647, was promulgated in 1985. The rules established administrative procedures for review of applications from hospitals to obtain funds at a below market interest rate. The market interest rate fell shortly after the revenue bonds to create the fund were issued, and hospitals did not apply to the Health Care Equipment Loan Program because they could obtain loans at a lower interest rate elsewhere. Therefore, the rules were never used and the program never operated. The authority for the rules, Minnesota Statutes, section 446A.08, was repealed in 1994 (Minnesota Laws 1994, chapter 632, article 2, section 67), therefore, chapter 4647 is recommended for repeal.

Chapter 4610 – Disposition of the Dead

Minnesota Rules, chapter 4610, is necessary for the regulation of the removal, preparation, and transportation arrangements for disposition and the final disposition of dead human bodies for the purposes of public health and protection of the public as required by Minnesota Statutes, chapter 149A. Chapter 4610 defines the application process and requirements for mortuary science resident intern registration, mortuary science license, funeral director license, and funeral establishment license. The rules apply to both original and renewal application processes and prescribe associated fees. No changes are recommended to these rules, however, Minnesota Rules, chapter 4610 could be incorporated into Minnesota Statutes, chapter 149A.

Chapter 4650 – Health Care Cost Information System

Minnesota Rules, chapter 4650, is necessary to define reporting requirements for aggregated financial and statistical hospital data collected under the Health Care Cost Information System (HCCIS) as required by Minnesota Statutes, sections 144.695 to 144.703. Data collected under these rules are used to fulfill several statutory requirements including monitoring trends in acute care costs, the financial status of Minnesota hospitals, aggregate hospital utilization, and the impact of health care reform and cost containment strategies (Minnesota Statutes, chapter 62J). Additionally, data collected under chapter 4650 are used to implement multiple state grant programs and determine medical care surcharge assessments for hospitals (Minnesota Statutes, sections 144.1456 to 144.1484, and section 256.9657). Finally, these data are used to fulfill statutory requirements associated with regulation of hospital facilities, directed by Minnesota Statutes, sections 144.50 to 144.58. MDH is currently concluding a rules process that will result in amendments to chapter 4650. No amendments outside of the current rule making process are recommended at this time.

Chapter 4651 – Aggregate Provider Data

Minnesota Rules, chapter 4651, is necessary to define reporting requirements for provider data as required by Minnesota Statutes, section 62J.41. These data fulfill a critical part of annual monitoring of sources of revenue and spending categories, which is necessary to describe the

health care costs related to use of physician clinics in the state. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4652 – Aggregate Group Purchaser Data

Minnesota Rules, chapter 4652, is necessary to define reporting requirements for group purchaser data as required by Minnesota Statutes, section 62J.38. These data are a critical part of annual monitoring of sources of revenue and spending categories, which is necessary to monitor health care spending, revenues, and enrollments for Minnesota residents in health coverage. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4685 – Health Maintenance Organizations

Minnesota Rules, chapter 4685, is necessary for the regulation of HMOs. These rules work in coordination with various statutes that regulate HMOs (Minnesota Statutes, chapter 62D) as well as those that regulate health plan companies (e.g., Minnesota Statutes, chapter 62Q and parts of chapters 62A and 62M). As the Legislature has revised some statutes, specifically parts of chapter 62Q, corresponding provisions of chapter 4685 have been repealed. At this time we do not recommend changes to chapter 4685, since duplicate provisions have been repealed.

Chapter 4688 – Essential Community Provider

Minnesota Rules, chapter 4688, is necessary to define application procedures and to regulate essential community providers in conjunction with and as required by Minnesota Statutes, section 62Q.19. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4695.0100 to 4695.1600 – Health Occupations Program

Minnesota Rules, parts 4695.0100 to 4695.1600, set out the administrative process for the Human Services Occupations Advisory Council authorized in Minnesota Statutes, section 214.13. Though not currently funded, the Advisory Council could be activated by the Legislature at any time. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4747 – Alcohol and Drug Counselor Licensing

Minnesota Rules, chapter 4747, contains rules for licensing and regulating alcohol and drug counselors, and protecting the public by setting qualification and professional conduct standards for alcohol and drug counseling services. These rules are a critical portion of the licensing system operated by the Health Occupations Program. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 9000 – Office of Mental Health Practice; Mental Health Practice

Minnesota Laws 1991, chapter 292, article 2, section 70, subdivision 2, transferred rules adopted by the Board of Unlicensed Mental Health Service Providers to the Commissioner of Health to be used by the Office of Mental Health Practice (OMHP) until the Commissioner adopts new rules. The following changes are recommended.

Certain parts and subparts are recommended for repeal. Because OMHP does not have a filing process, parts 9000.0050, 9000.0110, 9000.0120, 9000.0130, 9000.0140, 9000.0150, and 9000.0160, which describe filing, are obsolete. Part 9000.0100, subparts 2 and 3, are also recommended for repeal because OMHP does not have an applicant process or a Board. Finally, part 9000.0100, subpart 7, and part 9000.0190, are recommended for repeal because the variance process is not recommended in OMHP statutes.

Part 900.0100, subparts 4, 5, and 6 (mental health services, provider and remuneration), reflect a give and take process of hammering out what "mental health services" means and what it does not mean. The rules clarify the existing statutory definitions contained in Minnesota Statutes, section 148B.66, et. seq.. We recommend that these subparts remain in effect.

Part 9000.0170 (bill of rights), is necessary because a mental health client bill of rights is required by Minnesota Statutes, section 148B.71. This part references Minnesota Statutes, section 148B.46, which has been repealed. We recommend correcting the reference to section 148B.71. Other than this correction, we recommend this part remain in effect.

Administrative Uniformity Rules under Minnesota Statutes, chapter 62J (Exempt from the rulemaking process)

1) Minnesota Standards for the Use of the Health Care Financing Administration (HCFA) 1500 Claim Form Manual, defined by the Commissioner of Health as required by Minnesota Statutes, section 62J.52, subdivision 2, paragraph (b).

This manual is used by Minnesota health care payers and providers to uniformly complete the HCFA 1500 claim form. This reduces administrative costs for the health care system. This manual is developed by the Minnesota Administrative Uniformity Committee (AUC) and defined by the Commissioner of Health. This manual is revised every two years. We recommend no changes outside of the current revision process.

2) Minnesota Standards of Use: Manual for the American Dental Association (ADA) Claim Form as required by Minnesota Statutes, section 62J.52, subdivision 3, paragraph (b).

This manual is used by Minnesota dental payers and providers to uniformly complete the ADA claim form. This reduces administrative costs for the health care system. This manual is developed by the Minnesota Administrative Uniformity Committee (AUC) and defined by the Commissioner of Health. This manual will be revised and updated in 2001. We recommend no changes outside of the current revision process.

Finance and Administrative Services Division

Chapter 4670 – Merit System Rules

Minnesota Rules, chapter 4670, provide a merit system of personnel administration for county health agencies. The rules cover such areas as classification of positions, compensation, recruitment and examination, certification and appointment, separations and appeal procedures, and, in general, provide standards for agencies to follow so as to ensure compliance with the Federal Standards for a Merit System of Personnel Administration (5 Code of Federal Regulations, part 900).

Over the past several years, we have repealed language that is no longer useful or necessary. Other amendments to the rules have increased local flexibility and have allowed county appointing authorities to use their own county personnel policies, where appropriate. We have no suggestions for further changes at this time and recommend these rules remain in effect.

Public Health Laboratory

Parts 4615.0300 to 4615.0760 – Tests of Infants for Inborn Metabolic Defects

Minnesota Rules, parts 4615.0300 to 4615.0700, address testing of infants for inborn metabolic errors. These rules describe the responsibilities of hospitals, physicians, and MDH to ensure that all newborn infants are screened for treatable genetic/metabolic disorders to prevent mental retardation, developmental disabilities, and/or infant death. The newborn screening system in Minnesota has detected and confirmed disease in approximately 50 infants annually.

We recommend minor changes to reflect advances in newborn screening. For example, the rules require screening for five particular disorders. In 1999, the Minnesota Legislature approved funds for MDH to purchase advanced technology (*i.e.* a tandem mass spectrometer) to screen for up to twenty additional treatable genetic disorders. The utility, accuracy, and facility of pilot studies using tandem mass spectrometry compel us to recommend incorporating this expanded list of disorders into the rules. Another component in the rules that needs revision is the role of treatment control tests for diagnoses and treatment. Although the existing rules indicate a role for MDH in providing these tests, the expertise of Minnesota's medical community in diagnosing metabolic disorders obviates a role for MDH at the treatment stage. Other than minor changes, we recommend these rules remain in effect.

Chapter 4740 – Laboratories: Accreditation Requirements

Minnesota Rules, chapter 4740, addresses the certification of environmental laboratories that provide data to the State of Minnesota. The State of Minnesota requires that laboratories that perform water, soil, and waste testing for government agencies for regulatory purposes must be certified. The MDH Environmental Laboratory Certification Program certifies laboratories that have provided assurance that appropriate systems are in place to generate reliable data.

We recommend minor changes to reflect continual improvements in the program and the evolving regulations specified by state and federal agencies. For example, the rules specify the

certified test categories and list specific analytes and specific government programs. The rules need to be revised to reflect additional certified test categories identified by updated regulations. Moreover, the rules specify the administrative procedures and requirements for certification, and these need to be updated to reflect current regulations and improvements that make the process less cumbersome and more effective in demonstrating quality assurance in laboratory data. Other than minor changes, we recommend these rules remain in effect.

Facility and Provider Compliance Division

General Considerations for Rules on Hospitals, Nursing Homes and Other Health Care Facilities

Over the past several years, the Legislature has raised a number of issues regarding MDH's nursing home regulatory program. These discussions have resulted in requirements that MDH identify areas where rules create undue burdens on providers, that MDH initiate efforts to create alternative survey procedures, and that steps be taken to minimize the paperwork burden in nursing homes. Many of these activities will continue into the future.

While we believe that some chapters should remain in effect, this does not mean that we are unwilling to analyze or revise specific provisions. This would be a preferred way for dealing with many of the health facility licensure provisions. The Legislature has directed that MDH develop licensure programs for a variety of health care facilities. This process necessitates the development of the operating standards and, in many cases, these standards need to be specific. There are several reasons for this specificity. First, there is an obligation on MDH's part to make sure that standards are as clear as possible. Many of the physical plant rules include detailed specifications that put the providers and their architects and engineers on notice as to the exact requirements. Second, while specificity may curtail creativity, we believe that the standards in the rules are the minimum requirements that the legislature expected us to develop. For that reason, we have provisions relating to the contents of the records to ensure that residents are assessed and properly evaluated, that treatment requirements are clearly identified, and that there is a process to verify that care has in fact been provided. We will be working with various stakeholders to continue to find ways to minimize the paper burden, including the better use of technology for charting and documentation. If decisions were made to eliminate the rules that require certain records and certain record keeping standards, there is a risk that the standards would be too vague to enforce and the risk that resident care would be jeopardized. Another reason for the detail in many of the rules is the fact that there is the legislative expectation that facilities are surveyed, any noncompliance is identified, and actions are taken to enforce the rules if corrections are not made. The enforcement concerns necessitate that the rules clearly describe the requirements and expectations imposed on the various provider categories.

During the last legislative session, MDH submitted a report to the Legislature, Proposals for Improving the Nursing Home Regulatory Process, January 15, 2001, which addressed some of the concerns to reduce the regulatory burden on providers while still meeting the objectives of the Legislature to protect patients and residents in these facilities. One of those suggestions was

to have ongoing discussions, which could identify specific problems with specific rules. This would allow for clarification of the rules or for changing the rules in a more limited fashion.

MDH recommends that the facility licensure rules identified remain in effect. All of these rules comprise minimum standards to protect the health and safety of patients and residents, provide notice to providers of MDH's expectations, allow for an objective evaluation during the survey process, and are capable of enforcement in situations where compliance is not attained.

Chapter 4638 – Health Care Facilities Generally

Minnesota Rules, chapter 4638, relates to the keeping of pet animals in health care facilities. The rules outline the conditions that must be met by a health care facility to keep pet animals on the premises. Since this rule applies to all health care facilities, a separate rule chapter was established at the time of promulgation.

Since adoption, there have been no problems associated with the implementation of these rules. These rules provide flexibility to a facility to determine whether pets will be on the premises, require consultation with staff and patients and residents, and specify conditions for keeping the pet animals. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4640 – Hospital Licensing and Operation

Minnesota Rules, chapter 4640, contains the licensure rules for hospitals. The operational provisions of these rules apply only to state licensed facilities, while the physical plant requirements are applicable to all licensed hospitals. (See discussion for Chapter 4645.) The provisions of the rules only apply to state operated hospitals. Minnesota Statutes, section 144.55, subdivision 3, provides that the provisions of the federal Medicare regulations for hospitals be used as the state licensure rules for all other hospitals. The rules do establish minimum operational provisions for the state hospitals. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4642 – Medical Records

Minnesota Rules, chapter 4642, specifies the portions of an individual medical record that must be maintained on a permanent basis. The legislature directed MDH to promulgate the rules to specifically delineate the portions of the medical record that need to be maintained on a permanent basis. The rules are important to ensure that there will be access to this information by the subject of the data or by other family members. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4645 – Hospital Construction and Equipment

Minnesota Rules, chapter 4645, establishes the minimum physical plant requirements for all hospitals. These provisions are reviewed during the plan review process for new construction.

During the 2001 legislative session, a law was enacted that provided waiver authority for these physical plant provisions. This provision will provide greater flexibility to MDH.

MDH realizes that the provisions of the physical plant rules are old, however, an immediate need to revise the rules has not arisen. With the addition of the waiver authority, we believe that these rules will continue to establish minimum assurances for health and safety in the physical plant but also allow for the use of innovative designs. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4655 – Boarding Care Homes

Minnesota Rules, chapter 4655, establishes the rules for the operation of boarding care homes. These facilities provide care to individuals who need personal or custodial care. The provision of nursing care is not required to meet the needs of these residents. These rules establish the minimum standard for facility operation and include provisions relating to the administration of the home, resident rights, administration of medications, record keeping provisions, nutrition and dietary concerns, and maintenance of the facility. The rules are designed to protect the health and safety of the residents.

In addition, this chapter did contain provisions relating to the relocation of residents from nursing homes and boarding care homes, parts 4655.6810 to 4655.6830. These provisions were repealed during the 2001 legislative session when new provisions covering closure situations were included in state law. (See Special Session Law 2001, chapter 9, article 5, sections 9,10, and 41.) We have no suggestions for further changes at this time and recommend these rules remain in effect.

Chapter 4656 – Medical Assistance Program

Minnesota Rules, chapter 4656, establishes the responsibilities of nursing homes, certified boarding care homes and MDH relating to the case mix reimbursement system for these facilities. The rules establish the criteria for resident case mix classifications, the assessment and audit procedures, and the process to request reconsideration. These provisions are essential to the ongoing reimbursement of these long-term care facilities.

Provisions of the rule will either be repealed or amended during the development of the new reimbursement process for nursing homes. The new system will rely on currently required federal resident assessments and will eliminate the need for the state case mix assessment required under current law. This will reduce the paper work burden to nursing staff in these facilities. Other than these possible changes, we recommend these rules remain in effect.

Chapter 4658 – Nursing Homes

Minnesota Rules, chapter 4658, establishes the rules for the operation of nursing homes. These rules establish the minimum requirements to protect the health and safety of residents in these facilities. The rules address the operation and management of the facility and include, among others, the following provisions: minimum staffing requirements; standards for the various

services in the nursing homes, such as nursing, dietary and social services; requirements for resident assessment and care planning; provisions for the protection of resident rights; and the maintenance, safety and sanitary condition of the physical plant. This chapter also contains the rules relating to physical plant construction.

These rules were revised and amended several years ago to better conform to the federal regulations. This project involved participation from all stakeholder groups and adoption of the revised rules was generally noncontroversial.

These rules are necessary to protect the health and safety of residents. The rules establish the standards that are evaluated during the time of the survey. While it has been suggested that the licensure rules be repealed and that the state rely solely on the federal provisions, this approach has some risks. First, not all facilities are covered by the federal standards, while the state licensure standards apply to all facilities. In addition, the elimination of state standards could increase the cost to MDH to survey these facilities. MDH's budget for this program is based on the percentage of time for federal versus state activity. If the state relied on the federal regulations for the purpose of licensure, state costs for the program could potentially increase from approximately 18% to 33%.

Over the past several years, there have not been major concerns raised about the contents of these rules. There have been concerns about the survey and enforcement process; however, federal law governs those provisions. MDH is continuing its efforts to address these issues at the federal level. MDH is willing to discuss changes to specific rules and believes that this process is the most appropriate mechanism to deal with concerns and protect resident health and safety at the same time. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4660 – Boarding Care Homes; Physical Plant

Minnesota Rules, chapter 4660, establishes the rules governing the physical plant of boarding care homes. These rules relate to the safety and sanitation of the facility and are intended to ensure that the health, safety, comfort, and well-being of residents is not jeopardized by the condition of the building. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4665 – Supervised Living Facilities

Minnesota Rules, chapter 4665, establishes the requirements for the operation of supervised living facilities. This licensure classification includes the "group homes" for the developmentally disabled, mentally ill, and chemically dependent residents.

The rules include provisions for the staffing of these homes, the evaluation and assessment of residents, proper medication procedures, physical plant concerns, and dietary issues. The facilities are also required to obtain a license from the Department of Human Services, which addresses the type of programming to be offered to the facility residents. While not as extensive as the requirements for boarding care homes or nursing homes, these rules are intended to protect

the health and safety of residents in these facilities. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4667 – Home Care Providers; Fees

Minnesota Rules, chapter 4667, establishes the fees that governed the temporary registration of home care providers prior to the full implementation of the licensure program. These rules are no longer required and are recommended for repeal.

Chapter 4668 – Home Care Licensure

Minnesota Rules, chapter 4668, establishes the standards for the operation of home care agencies. These rules identify the various classifications of home care providers ranging from individual providers to large professional companies. These rules also apply to hospice programs and assisted living providers. Like the other health facility licensure rules, these rules set out the minimum requirements that must be met by the licensed provider. The rules address staffing qualifications, training requirements, supervision standards, resident rights, and record keeping requirements.

MDH provides training on the rules, and has ongoing meetings with providers to discuss concerns with the rules. MDH has been working with hospice providers to develop changes to the rules. The rules are intended to make sure that home care clients receive care from competent staff that their needs are properly evaluated and that appropriate care is provided. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4669 – Home Care Licensure Fees

Minnesota Rules, chapter 4669, establishes the fee structure for home care licensees. These rules establish fee amounts based on the type of home care provider and, in some cases, on the revenues generated by the home care provider. Licensure fees are required for the operation of MDH's licensure activity. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4675 – Freestanding Outpatient Surgical Centers

Minnesota Rules, chapter 4675, establishes the requirements for the freestanding outpatient surgical centers. These facilities are not considered part of a licensed hospital. The rules address the requirements for the administration of the facility, medical staff provisions, and the design and safety of the physical plant. The rules are intended to protect the health and safety of persons receiving surgical services in these settings. We have no suggestions for changes at this time and recommend these rules remain in effect.

Chapter 4680 – Health Facilities Grievance Mechanism

Minnesota Rules, chapter 4680, establishes the requirement that hospitals and outpatient surgical centers have internal mechanisms for addressing and resolving patient complaints. The rules

establish the framework for this internal system and include provisions relating to patient notification, response times, and record keeping. These rules provide patients the option of utilizing the facility's internal complaint mechanism before filing a complaint with the state agency.

One provision of the rules should be repealed. Minnesota Rules, part 4680.1100, requires the facility to file a report with MDH on an annual basis. The statutory provision authorizing the report was repealed in 1996. (Minnesota Laws 1996, chapter 451, article 4, section 71.) Since the internal grievance mechanism is designed to enhance the rights of patients, other than part 4680.1100, we recommend these rules remain in effect.

Part 4735.0200 – Licensure Fees

Minnesota Rules, part 4735.0200, establishes the licensure fees for hospitals, nursing homes, and other health care providers. However, these fees have been subsequently set in statute. (See Minnesota Statutes, section 144.122.) The rule language is obsolete and these rules are recommended for repeal.

Chronic Disease Prevention and Control Division

Chapter 4606 - Cancer Surveillance System

Minnesota Rules, chapter 4606, establishes a process and assigns responsibility for the collection of data from medical providers on the occurrence of cancer in the state and investigating the occurrence of cancer. This data is used by MDH to monitor and report trends in cancer occurrence. The information is used by the Legislature and other policy makers, researchers, and by the health care industry. We are planning three changes to the rules at this time.

The Minnesota Cancer Surveillance System (MCSS) is different from nearly every other cancer registry in the world, in that we have not collected information on cancers unless there was microscopic confirmation. This has resulted in there appearing to be more deaths due to pancreatic cancer than the number of new cases. We have received funding from the federal Centers for Disease Control and Prevention for us to begin collecting information on cancers without microscopic confirmation. Minnesota Rules, part 4606.3302, subpart 5, needs to be changed to include non-microscopically confirmed cancers in the definition of required case reports.

Data items related to cancer stage will change in 2003. This is a national coding standard change which will be required of all hospital-based cancer registries regardless of the MCSS requirements. Minnesota Rules, part 4606.3304, subparts 1 and 1a, will need to be changed to specifically require these items. ("Collaborative Staging" codes instead of just general summary stage and TNM stage.)

The new federal health care information privacy rules, which health providers must comply with by April 2003, appears to limit the legally-required disclosures of medical records "to the

relevant requirements of such law." (Health Insurance Portability and Accountability Act (HIPAA) privacy rules, 45 Code of Federal Regulations, Subtitle A, Subchapter C, section 164.512(a)(1).) Pathology laboratories in Minnesota are beginning to interpret the provision to mean that they cannot allow access to pathology reports unless the pathology lab has identified the result as containing a "reportable" diagnosis. This restriction will make it impossible to perform completeness audits, because the case finding sources (not the already-reported data) need to be reviewed by central registry staff to identify "missed" cases. Minnesota Rules, part 4606.3305, subpart 3, will need to be changed to clarify that MCSS has this right of inspection.

Other than the three planned changes, we recommend these rules remain in effect.

Community Health Division

Parts 4615.3400 to 4615.3600 – Termination of Pregnancy

Minnesota Rules, parts 4615.3400 to 4615.3600, have been in place since the 1970s and the data generated from these reports have been used by MDH to help assess overall public health trends. The governing statute and supporting rules applied only to ambulatory facilities "devoted primarily" to terminating pregnancy on an outpatient basis. Throughout this time, MDH has published an annual report of summary data generated by this reporting system.

The 1998 Legislature passed Minnesota Statutes, chapter 145, sections 145.4131 to 145.4136, "Recording and Reporting Abortion Data." This statute required reporting of abortions by, "A physician performing an abortion or a facility at which an abortion is performed. . . ." (Minnesota Statutes, section 145.4131, subdivision 2.) Further, the statute specifically spoke to the then-existing reporting system, "Nothing in this section shall be construed to preclude the voluntary or required submission of other reports or forms regarding abortions." (Minnesota Statutes, section 145.4131, subdivision 3.) As MDH implemented the 1998 law, it carefully compared the requirements of the statute with those of the existing rules. Combining the two reporting systems into one avoided duplication and ensured that the combined reporting system would provide better information. This process resulted in a very recent comprehensive review of the existing rules and how they related to new similar-subject statutory directives. The existing rules are consistent with the 1998 statute, are still necessary, and do not require changes. We recommend these rules remain in effect.

Chapter 4736 – Local Public Health Act

Minnesota Rules, chapter 4736, makes explicit the planning, reporting, and personnel standards and processes in order to qualify for and maintain eligibility for a public health subsidy that Minnesota Statutes, chapter 145A, authorizes to those local governments that have formed Community Health Boards. The rules are used every two years as part of the formal planning and planning update processes. Information generated through the reporting system is used annually by MDH and by the Legislature to monitor the performance of Minnesota's local public health system. The rules are actively used and no problems have arisen that would require

amendment of the rules. Because they are in continuous use, we recommend these rules remain in effect.

Chapter 4763 – Medical Education Assistance Programs

Minnesota Rules, chapter 4763, governs the State of Minnesota Loan Forgiveness programs for health professionals who agree to practice in areas of the state with shortages of these professionals. The rules implement the statutory programs used to encourage health care providers to practice in rural areas of the state or in nursing homes. (Minnesota Statutes, sections 144.1494 to 144.1496.) The programs include the Rural and Urban Physician Loan Forgiveness Program, the Midlevel Practitioner Loan Forgiveness Program, and the Nurses in Nursing Homes Loan forgiveness Program. The programs were transferred to MDH from the Higher Education Coordinating Board in the mid-1990s. In 2000, MDH updated and amended the rules, so there has been a recent comprehensive review and adoption process. The rules were adopted as non-controversial and they are current and in active use. We have no suggestions for further changes at this time and recommend these rules remain in effect.

Family Health Division

Part 4615.0800 – Reporting of Maternal Deaths

Minnesota Rules, part 4615.0800, requires physicians and hospitals to report maternal deaths to MDH. Under Minnesota Statutes, section 145.901, MDH has the authority to conduct maternal death studies to assist with the planning, implementation, and evaluation of medical, health, and welfare service systems, and to reduce the numbers of preventable maternal deaths in Minnesota. The reporting requirement in the rules is the only feasible method of identifying such deaths, which are rare events. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4615.0900 to 1615.2000 – Early and Periodic Health and Developmental Screening Programs

These rules were repealed, effective October 16, 2000.

Parts 4615.2100 to 4615.3300 – Maternal and Child Nutrition Act of 1975

These rules were repealed, effective October 16, 2000.

Chapter 4617 – WIC Program

Minnesota Rules, chapter 4617, governs the Special Supplemental Food Program for Women, Infants and Children (WIC Program), which is a federal nutrition program administered in Minnesota by MDH. The WIC program should remain in effect in Minnesota. It is an important program that has been shown to improve the health of infants, young children, and pregnant and breastfeeding women.

There are three types of WIC rules in chapter 4617: rules governing local agencies that contract with MDH to provide nutrition services to participants; rules governing retail vendors that accept WIC vouchers in exchange for approved foods; and rules governing the process for approving foods. These rules are needed because the federal regulations governing the WIC Program give the states considerable discretion in administering the program. (Code of Federal Regulations, title 7, part 246.) For example, the rules are used to decide how to select local agencies and how to decide which retailers should be authorized as WIC vendors. The rules governing vendors attempt to ensure that vendors provide approved foods to authorized persons, at appropriate prices.

We are in the process of updating the rules governing local agencies and vendors in order to simplify local agency operations and to address recent changes in federal regulations. Some portions of the current rules will be repealed as part of the updating process. We have no suggestions for further changes at this time and recommend the rules governing WIC, as a whole, remain in effect.

Chapter 4643 – Traumatic Brain and Spinal Cord Injury

Minnesota Rules, chapter 4643, prescribes requirements applicable to the statewide traumatic brain injury and spinal cord injury registry, including what information must be reported, who is required to submit reports, when reports must be submitted, the provision of registry data to public and private entities, and fees to be charged for compiling or analyzing registry data. These rules implement Minnesota Statutes, sections 144.661 to 144.665, which require the Commissioner to establish and maintain a central registry of persons who sustain traumatic brain injury or spinal cord injury. The data collected through the registry are used to develop and improve injury prevention, treatment, and rehabilitation programs and provide information to persons with traumatic brain injury or spinal cord injury regarding supportive services. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4700.1900 to 4700.2500 – Family Planning Special Project Grants

Minnesota Rules, parts 4700.1900 to 4700.2500, prescribe requirements for family planning special project grants, establish minimum standards for family planning services supported by family planning special project grant funds, and provide criteria for review of family planning special project grant applications. These rules implement Minnesota Statutes, section 145.925, which authorizes the family planning grants program and requires MDH to promulgate rules to implement the statute. As this program can be controversial, having rules in place to govern its operation is essential. We have no suggestions for changes at this time and recommend these rules remain in effect.

Parts 4700.2600 to 4700.4000 – Grants for Maternal and Child Health Services

Minnesota Rules, parts 4700.2600 to 4700.4000, establish a process for allocating federal maternal and child health funds and state funds in the form of grants to assist in establishing and maintaining maternal and child health services. These rules implemented a previous statute regarding the same grant funds and should have been revised several years ago when the statute

was changed. However, we sought further statutory changes in the 2001 session and had planned to revise or repeal the rules once the new statute was in place. Our proposed language did not pass, therefore we will shortly be considering whether to revise the rules to correspond to the current statute or to repeal them.

Chapter 4705 – Services for Children with Handicaps

Minnesota Rules, chapter 4705, specifies criteria, procedures, and responsibilities relating to applicant eligibility, applicant cost-sharing, and reimbursement to service providers for services authorized for children with physically handicapping conditions by the Services for Children with Handicaps program. (Now known as Minnesota Children with Special Health Needs.) These rules are out-of-date and the amendment process will be initiated within the next year.

Infectious Disease Prevention and Control Division

Chapter 4605 – Communicable Diseases

Minnesota Rules, chapter 4605, establishes a process and assigns responsibility for reporting, investigating, and controlling communicable diseases. Physicians, health care facilities, and medical laboratories are required to report cases of communicable disease within one working day following diagnosis, except for those diseases that must be reported immediately by telephone. For some of the reportable diseases, isolates/specimens must also be submitted to MDH. MDH investigates the occurrence of communicable disease cases to verify the existence of disease, determine the source of the disease-causing agent, identify unreported cases, locate contacts of cases, identify those at risk of disease, determine necessary control measures, and inform the public if necessary. We are in the process of adopting the following changes to the rules at this time.

- The rules should require specimen or specimens containing the viable agent of all reportable diseases to be submitted to MDH for further characterization. New test methods have been developed and are being used by laboratories that no longer result in the isolation of a viable agent. MDH needs an agent to conduct additional tests that allow for better tracking of diseases in the population for discovery of common-source outbreaks, to monitor antibiotic resistance, and to identify and provide treatment for infections.
- The rules should require immediate notification to MDH by telephone for selected infectious diseases for which there is a narrow window of time after exposure when treatment is effective. In particular, the rules should be updated to require notification to MDH by telephone of several potential bioterrorism agents that are not currently mandated.
- The rules should add varicella (chickenpox) as a reportable disease. Monitoring cases of this disease will provide an opportunity for intervention and outbreak control through vaccine use (which was licensed in 1995), a review of vaccine and vaccine program effectiveness, and the ability to identify pockets of disease.

- The rules should add invasive *Escherichia coli* infection in neonates (less than 7 days of age) as a reportable disease. *Escherichia coli* is one of the most common causes of neonatal sepsis and meningitis. Monitoring cases of this disease will provide important information about the level of disease in Minnesota, including the incidence of antibiotic resistant infections and information on perinatal risk factors.
- The rules should add the reporting of pregnancy status and expected date of delivery for cases of reportable diseases. There are a number of reportable diseases in where the potential for mother to fetus transmission has been documented, which can lead to severe medical consequences for the infants, including death.

We are in the process of proposing revisions to the rules and strongly recommend they remain in effect.