STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

IN THE MATTER OF PROPOSED RULES
RELATING TO THE REPORTING,
INVESTIGATION, AND CONTROL
OF DISEASE IN THE STATE.

STATEMENT OF NEED
AND REASONABLENESS

"The Minnesota Commissioner of Health (hereinafter "Commissioner"), pursuant to Minnesota Statutes 14.05 and 14.21 and rules 1400.0200-1400.0900 (formerly 9MCAR 2.101-108), presents facts establishing the need for and reasonableness of the above rules adoption and amendment.

In order to adopt the proposed rules, the Commissioner must demonstrate that she has complied with all the procedural and substantive requirements of rulemaking. Those requirements are that: 1) there is statutory authority to adopt the rule, 2) all necessary procedural steps have been taken, 3) the rules are needed, 4) the rules are reasonable, and 5) any additional requirements imposed by law have been satisfied. This statement demonstrates that the Commissioner has met these requirements.

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## 1. STATUTORY AUTHORITY.

The statutory authority of the Commissioner to adopt these rules is briefly noted below. The specific statutory authority for each rule or rule amendment is discussed in detail as part of the rule-by-rule justification.

- Minnesota Statute 144.05 provides the Commissioner with the authority and assigns the responsibility for development and maintenance of an organized system of programs and services for protecting, maintaining, and improving the health of the citizens.

- Minnesota Statute 144.0742 authorizes the Commissioner to enter into contractual agreements with any public or private entity for provision of statutorily prescribed public health services by the department.

- Minnesota Statute 144.12 authorizes the Commissioner to adopt reasonable regulations related to treatment of persons suffering from communicable diseases; the collection, recording, and reporting of vital statistics; and the furnishing of related information.

## 2. STATEMENT OF NEED.

*"The Government (Statisticians) are very keen on amassing statistics--they collect them, add them, raise them to the nth power, take the cube root, and prepare wonderful diagrams. But what you must never forget is that every one of these figures comes in the first instance from the village watchman who puts down what he damn pleases."*

*- Sir Josiah Stamp, 1929*

Disease surveillance (the collection, collation, and analysis of reports of disease and the dissemination of these data to those with a need to know) and organized efforts for disease control began in the United States over 100 years ago. In 1878, an act of Congress authorized the Public Health Service to collect morbidity reports for use with quarantine measures against pestilential diseases such as cholera, smallpox, plague, and yellow fever. Over the years there have been periodic revisions in the methods of surveillance and dramatic changes in control strategies. It has been about 50 years since State Rules and Regulations: 4735.0010 and 4735.0020 (formerly Chapter 1 (MHD 1 & 2) and Chapter 20 (MHD 316-328)) have been substantially reviewed and revised for rules adoption and amendment. The type of revisions which are made include additions and deletions to the list of reportable diseases, changes in quarantine measures provided, and updating the provisions of the rules to make them consistent with recent legislation, medical practice, and methods of electronic data processing.

The needs for each specific provision in the proposed rules is addressed in the rule-by-rule justification. It is the Department's position that the need of all rules proposed at this time is obvious and well established.

## 3. COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS.

Minnesota Statutes Sections 14.05-14.12 and 14.21-14.28 and rules of the Office of Administrative Hearings specify certain procedures which must be followed when an agency adopts or amends rules. Procedures applicable to all rules (Minnesota Statute Section 14.05-14.12) have been complied with by the Commissioner. The Commissioner has determined that the adoption and amendment of the rules in 4735.0010 and 4735.0020 is non-controversial and has elected to follow the procedures set forth in Minnesota Statutes Sections 14.21-14.28 which provide for an expedited process for the adoption of non-controversial administrative rule changes without the holding of a public hearing.

Procedural Rulemaking Requirements of the Administrative Procedure Act

Minnesota Statute Sections 14.10 requires an agency which seeks information or opinions in preparation for adoption of rules from sources outside the agency to publish a notice of its action in the State Register and afford all interested persons an opportunity to submit data or comments on the subject. In the State Register issue of Monday, June 14, 1982, p. 2254, the Commissioner published a "Notice of Intent to Solicit Outside Information and Opinions Concerning Revisions of Minnesota Rules: Chapter 1 (MHD 1 & 2)--'Duties of Local Health Officers and Country Boards of Health' and Chapter 20 (MHD 316-328)--'Communicable Disease.'" (renumbered as 4735.0010-4735.0020 and 4605.0200-4605.5100)

These rules do not incorporate by reference (Minnesota Statute Section 14.07 subd 4) text from any other law, rule, or available text or book. These rules do not duplicate any statutory language (Minnesota Statute Section 14.07 subd 5). The adoption of these rules will not require the expenditure of public money by local public bodies (Minnesota Statute

Section 14.11 subd 12) of greater than $100,000 in either of the two years following promulgation, nor do the rules have any impact on agricultural land. The adoption of these rules will not affect small businesses (Minnesota Statute Section 14.115).

Pursuant to Minnesota Statute Section 14.23, the Commissioner has prepared this statement of need and reasonableness which is available to the public. The Commissioner will publish notice of intention to adopt the rules without public hearing in the State Register and mail copies of the notice and proposed rules to persons registered with the Minnesota Department of Health pursuant to Minnesota Statute Section 14.14 subd 1. The notice will include the statements: a) that the public have 30 days in which to submit comments on the proposed rule; b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period; c) giving information pertaining to the manner in which persons shall request a hearing; and d) that the rule may be modified if modifications are supported by data and the views submitted.

If seven or more persons submit to the Minnesota Department of Health a written request for a hearing of the proposed rule, the agency shall proceed under the provisions of Minnesota Statute Section 14.13-14.20 and notice of hearing shall be published in the State Register.

If no hearing is required, the Commissioner will submit the proposed rule and notice as published, the rule as proposed for adoption, any written comments which have been received, and this statement of need and reasonableness to the Attorney General for approval as to its legality and form to the extent that it relates to its legality.

These rules shall become effective upon publication of a notice of adoption in the State Register.

Non-Mandatory Actions by the Commissioner

No other statute requires the Commissioner to comply with requirements in the promulgation of rules; there are two other actions which the Commissioner has taken which should be addressed:

First, the Commissioner, pursuant to the authority granted under Minnesota Statute Section 15.059, established in January 1983 a "Work Group to Revise the Reportable Disease Rules" as well as an earlier (November 1983) "Task Force to the Commissioner for Technical Recommendations for Acute Disease Surveillance and Control in Minnesota." Both of these groups were composed of representative physicians, nurses, administrators, and epidemiologists representing community health agencies, federal and state agencies, the University of Minnesota, and professional societies and associations as well as private medical practices. These groups provided direct advice on the methodologies and approaches considered best for disease surveillance and control in Minnesota.

Second, the Commissioner intends to notify persons who have not registered with the agency for receiving notices of rulemaking hearings. The notice of intent and copies of the proposed rules will be sent to: Community Health Services Agencies, Minnesota Society of Clinical Pathologists, Minnesota Medical Association, Minnesota Association of Practitioners in Infection Control, Minnesota Nursing Home Association, Minnesota Hospital Association, Minnesota Association of Health Care Facilities, and Minnesota Veterinary Medical Association.

## 4. GENERAL STATEMENT OF REASONABLENESS.

In order to adopt administrative rules, an agency must demonstrate that the proposed rules are reasonable. Rulemaking is a process which primarily involves policy decisions. There are many differing policy perspectives and biases which can, therefore, result in many reasonable ways to address a subject covered by administrative rules.

These rules provide a framework within which the Commissioner can conduct and evaluate disease surveillance and control efforts. The following definition of surveillance has served as a principal guide in drafting these rules:

> "SURVEILLANCE IS A DYNAMIC PROCESS TO PROVIDE DATA FOR ANALYZING AND INTERPRETING THE OCCURRENCE OF HEALTH RELATED EVENTS IN A DEFINED POPULATION AS INFLUENCED BY HOST-AGENT-ENVIRONMENTAL FACTORS. THE PROCESS MAY UTILIZE SEVERAL ALTERNATIVES, REQUIRING ONE OR A COMBINATION OF METHODS AND TECHNOLOGIES, BASED ON THE PURPOSES, THE DEGREE OF CONFIDENCE DESIRED FOR THE RESULTS, THE PROBLEMS AND THE AVAILABLE RESOURCES. (Health related events include not only clinical disease but also subclinical conditions and serologic, genetic, microbiologic, pathologic, and biochemical data as well as data to aid in determining outcomes such as death, illness, disability, productivity, and benefit/cost ratios.)"
>
> - Professor R. K. Anderson, D.V.M., M.P.H.
> University of Minnesota, 1982

These rules have been developed to promote the concept of specific surveillance activities for specific purposes, within specific agent-host-environment situations. The rules discourage the concept of one, monolithic system which uses the same methods, the same technology, and the same population to fulfill all surveillance needs.

The Commissioner of Health asserts that the rules proposed here are reasonable. They have a rational basis in law, medicine, and public health practice; do not represent arbitrary or capricious policies; and meet every procedural and substantive requirement for adoption.

## 5. RULE-BY-RULE JUSTIFICATION.

4605.7000 DEFINITIONS.

Terms used in the rules are now defined in order to make the provisions of the rules more understandable.

4605.7010-4605.7020 PURPOSES AND SCOPE.

As stated in the proposed rules, the purpose is to establish a process and assign responsibility for reporting, investigating, and controlling disease. They are generally based upon the provisions of Minnesota Statutes Sections 144.05 and 144.12.

4605.0200-4605.0600 are deleted and replaced by 4605.7030-4605.7800 which represents revisions and expansions to update the previous provisions which were either inconsistent with current medical and public health practice and/or lacking a statutory basis.

4605.7030 PERSONS REQUIRED TO REPORT DISEASE.

Subparts 1-5. This paragraph and its listing of reportable diseases is revised and expanded to include reports from physicians, health care institutions, medical laboratories, and to allow for comprehensive reports and reports from veterinarians. This section is based upon MN Stats 144.05 and 144.12. Specific statutory basis is found for tuberculosis (144.42-471;246.27-28), Reye Syndrome (144.659), and lead poisoning (144.34).

4605.7040 DISEASES AND REPORTS.

Two epidemiologically-related diseases are deleted from the list of reportable diseases. Smallpox: This disease no longer exists in the world; and Chickenpox (only patients over 16 years of age): early symptoms of cases were often similar to smallpox and these patients were, in the more recent past, recruited as blood donors for making immune serum derivatives for immuno-compromised persons, a method which has been replaced by more efficient commercial methods.

4605.7050

This section is revised to update the language only. This section is based upon MN Stat 144.05 a & c; 144.12; 144.34; and 145.03-145.17.

4605.7060

This is a new provision which is intended to provide reports on diseases which are "rare" or "exotic" to Minnesota, are public health problems, and which would be too lengthy and speculative to include with the reportable disease list in (a). This section is based upon MN Stat 144.05 a & c; 144.12; and 144.14.

4605.7070

This section is revised as "Other Reports" to provide consistency with 4605.7040. This section is based upon MN Stat 144.05 a & c; and 144.12.

4605.7080

This section is a new provision which is intended to set out a procedure for the Commissioner to request reports of new and emerging diseases and syndromes which are not included in rules but are none-the-less of public health importance. This section is based upon MN Stat 144.05 a-c; and 144.12.

4605.7090

This section on reports is revised, expanded, and the specific report card format deleted in order to allow for reporting in different electronic data processing formats. This section is based upon MN Stat 144.05 and 144.12.

4605.7100-4605.7300

These sections are revised and expanded to include forwarding of reports to the State, maintenance of records by the Commissioner, and reports from the Commissioner to local boards of health. This section is based upon MN Stat 144.05 a-c, f, g, & h; and 144.12.

MHD317 (4605.0700)

This section is deleted from rules since quarantine placards are not appropriate in any way to disease control or medical practice at this time.

MHD318 (4605.0800)

This section is deleted since knowledge of disease transmission at this time indicates no additional risk of these diseases in hotels or in the general population living in houses or apartments. Special precautions would be covered under revised 4605.7400.

MHD319 (4605.0900-4605.1000)

This section is deleted since the precautions of disinfection, removal, and placarding of this type and specificity are not necessary. Special precautions would be covered under revised 4605.7400.

MHD320 (4605.1100)

This section is deleted since modern antibiotics, large-scale milking and milk handling, and routine pasteurization eliminate the need for this rule. Special precautions would be covered under 4605.7400.

MHD321 (4605.1200)

This section is deleted since ordering curtailment of public gatherings and contact is no longer necessary to control disease. Special precautions would be covered under 4605.7400.

4605.7400 PREVENTION OF DISEASE SPREAD.

This section provides for physician (or, in the absence of a physician, the Commissioner) responsibility for ensuring isolation as necessary to prevent disease transmission.

This is a new section which replaces the specific quarantine and epidemic precautions of the several deleted sections. The logic of (a) in this section is based upon the assumption that isolation is a medical practice decision and that any other necessary quarantines or prohibitions on gatherings would be brought to district courts pursuant to the applicable statute and as authorized by MN Stat 145.075. This section is based upon MN Stat 144.12, subd 1(7) and 2.

4605.7500 DISEASE INVESTIGATIONS.

This section is revised and specifies investigation of disease as a duty of the Commissioner. This section is based upon MN Stat 144.05 a-c; 144.12, subd 1 & 2; 144.14; 144.34; 145.04; and 145.05.

4605.7600 **(See MHD 326h--4605.2500--on page 12)**

4605.7700 and 4605.7800 **(See MHD 326--4605.3600-4605.5100--on page 13)**

MHD322 (4605.1300)

This section is deleted as there is no specific statutory basis for broad exclusion of children from school and providing for such follow-up reports as described in this rule.

MHD323, MHD324, MHD325 (4605.1400-4605.1600)

These sections are deleted because currently available antibiotics and current medical practice make these rules obsolete. Special precautions would be covered under the revised 4605.7400.

MHD326 (4605.1700-4605.5000)

The following sections are deleted or replaced for the reasons stated:

a. (4605.1700) This section is deleted since polio is virtually eliminated in the U.S. and best controlled through immunization and thorough case follow-up. Special precautions would be covered under 4605.7400.

b. (4605.1800) This section is deleted since shaving brushes made from horsehair are no longer available.

c. (4605.1900) This section is deleted since chickenpox is no longer confused with smallpox (which no longer exists in the world). Special precautions would be covered under 4605.7400.

d. (4605.2000-4605.2100) This section is deleted since diphtheria is now treated effectively with medication and prevented by immunization. Special precautions would be covered under 4605.7400.

e. (4605.2200) This section is deleted since vector-borne encephalitis viruses present in Minnesota are not known to be transmitted from person-to-person via vectors or other modes. Special precautions would be covered under revised 4605.7400.

f. (4605.2300) This section is deleted because school immunization laws (MN Stat 123.70) have virtually eliminated measles in Minnesota. Special precautions would be covered under revised 4605.7400.

g. (4605.2400) This section is deleted because it is inaccurate; not all meningitis is "meningoccocus" (N. meningiditis). If special precautions are necessary, they would be covered under revised 4605.7400.

h. (4605.2500) This section is deleted and replaced by 4605.7600, an expanded section which clarifies and specifies species of risk, quarantine, and prophylaxis for rabies. This section is based upon MN Stat 144.05 c; 144.12 subd 1(7); 145.03; 145.05; 145.17; and 145.22.

i. (4605.2600) This section is deleted because currently available antibiotics and medical practice make the rule obsolete. Special precautions would be covered under the revised 4605.7400.

j. (4605.2700) This section is deleted because smallpox has been eradicated from the world.

k. (4605.2800) This section is deleted since trachoma (C. trachomatis), though infectious, is treatable with antibiotics and manageable by an informed patient. Special precautions would be covered under revised 4605.7400.

l. (4605.2900) This section is deleted as the provisions stated here are now covered by MN Stat 246.7 (1980) and 144.422 (1982).

m. (4605.3000) (1), (2), and (4) are deleted as they are no longer necessary requirements for the control of typhoid fever. Special isolation precautions would be covered in the revised 4605.7400.

**(3) N.B. 4605.3000 subpart (3) is being renumbered as 4720.3910 (formerly 7MCAR 1.149F). It is not being repealed. 4720.3600-4720.3900 already deals with public notification concerning public water supplies and the addition of this condemnation provision fits logically within the sense of that rule.**

n. (4605.3600-4605.5100) This entire section is deleted and replaced with new sections as reporting is included in the main list in revised 4605.7040 and other deleted sections are either statutorily unbased or inconsistent with the current state of medical practice. A new section--4605.7700 and 4605.7800--provide special provision for reporting and education of patients with syphilis, gonorrhea, and chancroid for reporting of cases in addition to routine reports.

4605.7700 represents an updating and revision of previous wording. This section is based upon MN Stat 144.05 a-c; 144.12 subd 1(7); 145.04; and 145.36.

4605.7800 represents a revision of previous wording to include all health care providers working with sexually transmitted disease patients and to clarify specifics of patient education. This section is based upon MN Stat 144.05 e; and 144.12 subd 1(7).

(4605.3100) This section is not being revised and is renumbered as 4605.7900.

(4605.3200) Whooping cough (pertussis) is effectively controlled with immunizations and antibiotics. Special precautions would be covered under 4605.7400.

(4605.3300) This section is not being revised and is renumbered as 4605.8000.

MHD327 and MHD 328 (4605.3400-4605.3500).

These two sections are deleted as the Statute upon which they were based (Minnesota Statute 123.69) expired on July 1, 1983, pursuant to Laws 1979, Chapter 292, Section 2 which reads as follows: "Sec. 2 Effective date. Minnesota Statutes 1978, Section 123.69, expires July 1, 1983."

4735.0100 (subp. 1-5) DEFINITIONS

Terms used in the rules are now defined in order to make the provisions of the rules more understandable.

The existing rule is revised and replaced with the new Sections entitled "Duties of the Commissioner" and "Duties of Local Board of Health."

4735.0200 DUTIES OF THE COMMISSIONER

Subpart 1. Clarifies that the Commissioner is responsible for disease surveillance, investigation, and control in the State pursuant to MN Stat 144.011, 144.05, 144.12, and 145.03.

Subpart 2. Pursuant to MN Stats 144.05, 145.03, and 145.031, the Commissioner may enter into agreements with local boards of health to perform her functions in collecting and analyzing surveillance data, conducting investigations, and controlling disease as the designated agent. This section sets out the requirement that the Commissioner establish criteria upon which performance will be based and termination of agreements if the duties and responsibilities set forth are not met.

Subpart 3. Pursuant to MN Stats 144.05, the Commissioner agrees to notify local boards of health of health hazards.

Subpart 4. Pursuant to MN Stats 144.05, the Commissioner will assist local boards of health.

Subpart 5. Pursuant to MN Statss 144.05 and 145.03, the Commissioner may suspend agreements with local boards of health during emergencies.

4735.0300 DUTIES OF LOCAL BOARD OF HEALTH.

Subpart 1. MN Stat 145.914 subd 6 and 11, as well as the above mentioned references, provide that local boards may request assistance from the Commissioner regardless of agreements as above and that the Commissioner will make personnel and technical assistance available to the local board.

Subpart 2. Provides, pursuant to MN Stat 144.05 and 145.914, for the reciprocal communication between the Commissioner and local boards of health concerning conditions which represent a public health hazard.

The following are specific justifications for the deletion of 4735.0010 and 4735.0020.

MHD1 (4735.0010) is repealed. Minnesota Statutes 145.911 to 145.921 places the responsibilities of local health offficer with the local board of health. The provisions of Stat 145.911 to 145.921 make it unnecessary to have annual meetings to discuss "general sanitary conditions."

MHD2 (4735.0020) is repealed. The local health officer references are no longer applicable (pursuant to Minnesota Statutes 145.911 to 145.921) and the duties listed in (a) through (h) are either no longer relevant or revised and updated in the proposed new rules (4735.0100-4735.0300) The specific justifications for (a) through (h) are the following:

(a) There is no need for reports of the "general" condition of counties relating communicable diseases, current medical practice, and the design and engineering of water supplies and sanitation systems. The revisions (4605.7000-4605.7800) will accommodate the need addressed here.

(b) This section is revised and updated in the proposed new rules for 4735.0100-4735.0300.

(c) This section is not necessary since there are specific requirements for birth records which are provided in Minnesota Statute 144.213 through 144.215 for procedures of local registrars and systematic record keeping.

(d) This section is not necessary since State and Federal laws related to inspections and regulation of such establishments are in effect.

(e) This section is revised to meet the provisions of Minnesota Statutes 145.911 to 145.921.

(f) Now covered in Minnesota Statutes 145.911 to 145.921.

(g) Same as (e) above.

(h) Same as (f) above.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

**In the Matter of Proposed Rules Relating to the Reporting, Investigation, and Control of Disease in the State.**

SUPPLEMENT TO THE STATEMENT OF NEED AND REASONABLENESS

As has been previously stated, there is a clear need for these proposed rules in order to update the list of specific diseases to be reported and to provide consistency with recent legislation, medical practice, and electronic data processing (Statement of Need and Reasonableness, page 4). Further, the development of these proposed rules was guided by a definition of surveillance which emphasizes a dynamic process for data collection and analysis and a flexible process using alternative resources for data. They promote the concept of specific surveillance activities for specific purposes within specific agent-host-environment situations (Statement of Need and Reasonableness, page 8).

A Notice of Intent to Adopt Rules and to Repeal Rules Without a Public Hearing along with the proposed rules and repealer were published on June 18, 1984, in S.R. 2690.

During the 30-day comment period, thirty-two comments were received. One comment (Attachment A) dealt with the relationship of the Commissioner and Local Boards of Health in 4735 but did not request a hearing. Another comment (Attachment B) offered several suggestions for adding additional clarity to the reporting of specific information but did not request a hearing. Thirty letters (Attachment C) objected to the omission of specific references to chiropractors from the proposed rules and requested a hearing. Discussions were held with representatives of the Board of Chiropractic Examiners and the Minnesota Chiropractic Association. Prior

to publication of the notice of a hearing as demanded by the thirty letters, the Chiropractic representatives proposed inclusion of the language now found in 4605.7030 subp. 6 (d). Six letters requesting withdrawal of earlier letters requesting a public hearing (Attachment D) were then received, allowing the Commissioner of Health to proceed with promulgation of these rules by the non-controversial method.

In addition to addressing the comments received, this supplement addresses the impact of these new rules on small business, specifically on veterinary practices and medical laboratories, pursuant to Minnesota Statute 14.115.

## RESPONSE TO COMMENT (A)

Chapter 4735 of the proposed amendment establishes a formal relationship between the Commissioner and Local Boards of Health for disease surveillance, reporting, and investigation. The Commissioner, as the State's health agency, has general authority and responsibility for the development and maintenance of an organized system of programs and services for protecting, maintaining, and improving the health of the citizens of the State. This authority includes establishing and enforcing health standards for the protection and the promotion of the public's health, such as reporting of disease. Minnesota Statute 144.05(c). Further, the Commissioner may adopt, alter, and enforce reasonable regulations for the preservation of the public health. Minnesota Statute 144.12 Subd. 1 and 2 and 145.918 Subd. 1(c). The Commissioner is permitted to share or delegate certain of her responsibilities to local boards of health. Minnesota Statute 145.01-145.05. However the CHS Act envisions a state system of guidelines and standards under which shared or delegated responsibilities are carried out on the local level. Minnesota Statute 145.911 Subd 1. The

Commissioner's role, therefore, is not only to assure that disease reports are collected and reviewed and epidemiologic investigations occur but also to create a unitary system for disease prevention and control which will operate throughout the state.

As for the suggestion that part 4735.0200 subp 2 be a separate section which would provide that the Commissioner and the local boards of health "shall enter" into written agreements as part of the CHS plan for sharing responsibilities under Rules 4635.7000 through 4165.7800, the statutory authority for such agreements uses the discretionary language "may enter." See Minnesota Statute 144.05, 145.03, 145.031, 145.55, and 145.918.

The final suggestion is that part 4735.0300 subp 1 be changed to give a local board of health discretion to request assistance from the Commissioner when a public health hazard exceeds the capacity of the local board of health to respond. While it is true that the enabling statutes cited above use discretionary language, the Commissioner in any case retains the final responsibility for disease prevention and control. Thus it is reasonable that when a health hazard exceeds the resources of the local board of health, the Commissioner may require the county to seek assistance.

**RESPONSE TO COMMENT (B)**

Suggestions were made for clarifying parts 4605.7030 (persons required to report) and 4605.7040 (reportable diseases) to avoid redundancy.

Regarding 4605.7030, there may at times be redundancy in reports of specific laboratory tests. However, the electronic system (computer) to be used for handling reports will be able to sort out redundant reports easily and thus allow less of a sorting requirement for laboratories which are reporting.

Regarding the suggestions for part 4605.7040, they are all four, good, clarifying suggestions and are incorporated into the proposed rules as follows:

R. -- Amend to read "(only invasive disease . . .)."

S. -- Amend to read "(viral types A, B, and nonA-nonB)."

T. -- Delete "types I and II."

BBB. -- Amend to read "(Rickettsia prowzakii and R. typhi)."

**RESPONSE TO REQUESTS FOR HEARING (C) AND WITHDRAWAL OF REQUESTS (D)**

The specific objections raised in the requests are addressed as follows:

4605.7000

Subpart 1. This definition places the responsibility for the diagnosis of disease (including both those diseases listed in 4605.7040 and those diseases which may be present in the population and represent a public health hazard) with physicians. The ability of a doctor of chiropractic to make a diagnosis of a disease referred to in these rules is not relevant since these diseases are not by law diseases which are diagnosed and treated by chiropractors. Compare Minnesota Statutes 148.01 and 147.)

Subpart 7. The most significant proportion of the specimens collected for medical laboratory examination are (a) collected through invasive procedures which are by law not included in chiropractic practice, (b) tests which if positive require treatment with drugs which are prescribed by a physician, and (c) unrelated to "abnormal articulations of the human body." See Minnesota Statute 148.01.

Subpart 8. Physicians diagnose and treat the diseases related to these rules. A chiropractor may, from time to time, recognize a disease

referred in these rules and report this knowledge pursuant to Minnesota Statute 148.08 and proposed part 4605.7070 or refer the patient to a physician who is required by proposed part 4605.7030 subp. 1 to report.

4605.7030

This section addresses reporting by specified persons, laboratories, or institutions as defined in 4605.7000.

4605.7060

(Same justification as 4605.7030.)

4605.7090

E. Physician name and address are fundamental for confirmation of diagnosis and surveillance follow up.

G. Reports from chiropractors would include their names here as making a report.

4605.7600

Subpart 1. Only physicians can prescribe anti-rabies prophylaxis; therefore, the responsibility of determination of exposure rests with the physician.

4605.7700

Venereal disease diagnosis, treatment, and the determination of failure of patients to undergo or complete therapy is the practice of medicine.

**THE FOLLOWING ADDRESSES THE MODIFICATION TO THE PROPOSED RULES WHICH ACCOMODATES THE CONCERNS OF THE CHIROPRACTIC COMMUNITY**

Part 4605.7030 subp. 6 is a change in the rules as originally published. The new subpart specifies the duty of health care providers to report (unless previously reported) their knowledge of the suspected existence of a disease listed in part 4605.7040 whose symptoms may be

recognized in the course of their particular practice. Part 4605.7030 provides specificity to the more general reporting requirement in part 4605.7070 which addresses any person having knowledge of disease which may threaten the public health.

The Commissioneer recognizes that knowledgeable, experienced, licensed health professionals other than physicians are able to recognize some of the signs and symptoms of the diseases listed in part 4605.7040. Part 4605.7030 subp. 6 is not, however, meant to imply or suggest that licensed health professionals, other than physicians, are required or allowed to diagnose or provide treatment for any of the diseases listed in 4605.7040, except as provided within the scope of their specific professional practices laws.

## IMPACT ON SMALL BUSINESSES

A concern for reducing or eliminating the impact of the proposed amendments on small businesses are reflected in the rules as follows.

Veterinary Medical Practices. Several veterinarians representing individual practitioners, a teaching and research institution, and the Minnesota Veterinary Medical Association (Drs. Ashley Robinson, Stanley Diesch, Stanley Hendricks, and R. K. Anderson) consulted with the Commissioner in the drafting of these rules in general and specifically were responsible for proposing the concept of veterinarian reporting contained in part 4605.7030, subp. 5.

The consultants considered the establishment of less stringent compliance or reporting requirements for small businesses, the establishment of less stringent schedules or deadlines for compliance or reporting requirements, the consolidation or simplification of compliance and reporting requirements, the establishment of performance standards for

small businesses to replace standards required in the rule, and the exemption of small businesses from any or all requirements of the rule. The resulting reporting requirement for veterinary medical practices was intentionally set up as a non-mandatory request for reports in order that the burden of participation in reporting for veterinarians is entirely voluntary. Therefore, it will have no impact on veterinary practices unless the individual veterinarian chooses to respond to a specific request of the Commissioner. Any further reduction or elimination of the impact of the disease reporting requirements on veterinary medical practices would be contrary to the statutory objectives that are the basis of the proposed rule amendments.

Medical Laboratories. The provisions in these rules for medical laboratory reports were designed in conjunction with Dr. Bertram Woolfrey who was the appointed representative of the Minnesota Society of Clinical Pathologists (principally, laboratory directors and medical technologists). Dr. Woolfrey was a member of the Commissioner's working committee which drafted these rules. Laboratorians at the Minnesota Department of Health and at other laboratories also sat on the committee.

The consulting laboratorians considered the establishment of less stringent compliance or reporting requirements, the establishment of less stringent schedules or deadlines for compliance or reporting, the consolidation or simplification of compliance or reporting requirements, the establishment of performance standards to replace operational standards, and the exemption of laboratories from any or all requirements of the rule. The resulting reporting requirements for medical laboratories allow for considerable flexibility by laboratories in terms of the format and way lab results are reported to the Commissioner. For example, an

extra copy of the lab slip or a composite computer printout are both considered acceptable reports. This flexibility eliminates the need for separate paperwork or increased data handling beyond that which is simply essential to proper laboratory record keeping. The resulting reporting requirements for medical laboratories cannot be made less simple or less constraining without invalidating the data to be collected and thus becoming contrary to the statutory objectives that are the basis of the proposed rulemaking.

The effects of the proposed rules on medical laboratories have also been reviewed by the members of the Minnesota Society of Clinical Pathologists through their communiques and at business meetings. The Society and its parent organization, the American Society of Clinical Pathologists, certify the training of professional laboratory workers.