5/8/95

State of Minnesota

Minnesota Department of Health

In the Matter of Proposed Permanent Rules Relating to Health; Disease and Syndrome Reporting, Minnesota Rules, parts 4605.7000 to 4605.7800

Statement of Need and Reasonableness

I. Background.

Since 1987 the National Academy of Science's Institute of Medicine has published three reports documenting the urgent need to improve our ability to identify infectious disease threats and respond to them effectively. Once expected to be eliminated as a public health problem, infectious diseases remain the leading cause of death worldwide. To address emerging infectious diseases the Centers for Disease Control and Prevention (CDC) has developed a plan that emphasizes surveillance, research and prevention (CDC. Addressing Emerging Infectious Diseases Threats, 1994).

The first goal - surveillance - calls for the prompt detection, investigation and monitoring of emerging pathogens. **This goal has prompted revision of the existing communicable disease reporting rules of the Minnesota Department of Health.**

The Institute of Medicine (which operates under a charter granted to the National Academy of Sciences by the Congress of the United States) in the 1992 publication "Emerging Infections: Microbial Threats to Health in the United States" states:

> The key to recognizing new or emerging infectious diseases, and to tracking the prevalence of more established infectious diseases, is surveillance. (Institute of Medicine, page 10)

The Institute of Medicine recommends the development and implementation of strategies to strengthen state as well as federal surveillance. Reporting, a computerized infectious disease database, and strong national and international coordination are recommended (Institute of Medicine, pages 15-17).

Surveillance of infectious diseases in the United States is heavily dependent on voluntary collaboration between CDC and state and local health departments, which the CDC notes depend on physician-initiated reporting of a limited number of specific, recognized infectious diseases.

According to the CDC:

> Timely recognition of emerging infections requires early warning systems to detect these diseases, so that they can be quickly investigated and controlled before they become a major public health crises. Prompt detection of these new threats requires careful monitoring by effective surveillance systems, a thorough understanding of trends in incidence and distribution of known infectious agents, and good communication among clinicians, medical laboratories, and public health systems. (CDC, Addressing Emerging Infectious Disease Threats, 1994, page 3.)

CDC notes that emerging infections, such as acquired immunodeficiency syndrome (AIDS) and tuberculosis vividly illustrate that no nation can be complacent about human vulnerability to the microorganisms with which we share our environment (CDC. Lyme disease, 1993) (CDC.Update: mortality attributable to HIV infection 1993) (CDC.Outbreak of acute illness - 1993) (CDC.Hantavirus infection 1993) (CDC.Update; Hantavirus pulmonary syndrome 1993) (CDC. Update: Cholera 1992) (CDC. Preliminary report: foodborne outbreak of *Escherichia coli* 0157:H7 1993) (CDC.Update: multistate outbreak of *Escherichia coli* O157.H7 1993) (CDC.Cholera associated with an international flight) (CDC.Drug-resistant *Streptococcus pneumoniae* 1993) (CDC.Imported cholera 1993) (CDC. Salmonella serotype Tennessee in powdered milk products and infant formula 1993)

♦ Since the early 1970s, the U. S. public health system has been challenged by many newly identified pathogens and syndrome, such as Lyme disease, legionnaires' disease, toxic shock syndrome, cryptosporidiosis, and most recently, hanta virus. (Minneapolis Star and Tribune, May 7, 1995)

♦ The incidence of many diseases widely presumed to be under control - such as cholera, dengue, yellow fever and tuberculosis has increased or spread to new regions. There have been reports of serious illness and at least one death due to cholera among international airline passengers arriving in California (CDC.Cholera associated with an international flight) (Minneapolis Star and Tribune, January 4, 1995).

♦ We may face the emergence of drug-resistant pathogens (St. Paul Pioneer Press, October 8, 1994).

♦ Our changing lifestyles have impacted disease monitoring and surveillance and reporting. The number of children in child care facilities has increase dramatically in the past decade, now numbering over 11 million. They are encountering more enteric infections such as hepatitis A, giardiasis, cryptosporidiosis, and respiratory illnesses. These are carried home and transmitted to other household members.

♦ The elderly, a normally vulnerable sector of our population, make up a growing portion of our population.

♦ Emerging infections transmitted by contaminated food and public water supplies have placed entire communities at risk. In early 1993, hamburgers contaminated with the bacterial pathogen *Escherichia coli* O157:H7 and served at a fast-food restaurant chain caused a multi-state outbreak of hemorrhagic colitis (bloody diarrhea) and serious kidney disease, resulting in the death of four children. In the spring of 1993 contamination of a municipal water supply with the intestinal parasite *Cryptosporidium* caused the largest recognized outbreak of waterborne illness in the history of the United States; an estimated 403,000 person in Milwaukee had prolonged diarrhea, and about 4,400 persons required hospitalization (St. Paul Pioneer Press October 13, 1994)(CID 1994:18 May Changing Epidemiology of Food-Borne Disease: A Minnesota Perspective)(JAMA, December 9, 1992).

♦ Exposure to certain animals has placed Americans at risk. Hantavirus pulmonary syndrome (HPS), first detected in southwestern United States in 1993, has been linked to exposure to infected rodents in over a dozen states. More than 50 cases have been detected and more than half of those infected have died (CDC. A New Hantavirus).

Lack of surveillance and limited availability of appropriate diagnostic tests interfere with public health efforts to prevent and control outbreaks reports the CDC (CDC Executive Summary, page 2).

Minnesota Department of Health (MDH) is proposing amendments to existing reporting rules to allow MDH to fully implement disease tracking and prevention programs and to maintain the effectiveness of its disease detection, transmission, and prevention programs (MDH.Disease Control Newsletter October 1994)

The proposed modification will allow MDH to fully participate in national surveillance and monitoring systems. In January of 1995, MDH was publically notified by the CDC that an emerging infections program network is being establishment and four states, Minnesota being one of them, were chosen to participate because they already have active disease tracking and prevention programs. Minnesota has agreed to expand its disease detection

and tracking system, to watch for signs of new disease and analyze unexplained death in previously healthy people. The system is expected to document infectious diseases as well as food-borne illnesses .

Minnesota's emerging infections program will be conducted through a community-wide network of individuals and organizations, and a key element of the effort will be stepped-up laboratory surveillance for potential infectious disease problems. Project participants include clinical laboratories, health professionals, hospitals, and other health care providers (The Health Connection, page 1).

II. Statutory Authority.

Authority for the commissioner of health to adopt and amend these rules is contained in:

Minnesota Statutes, section 144.05 GENERAL DUTIES OF COMMISSIONER; REPORTS.

The state commissioner of health shall have general authority as the state's official health agency and shall be responsible for the development and maintenance of an organized system of programs and services for protecting, maintaining, and improving the health of the citizens. The authority shall include but not be limited to the following:

(a) Conduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems;

(b) Plan, facilitate, coordinate, provide, and support the organization of services for the prevention and control of illness and disease and the limitation of disabilities resulting therefrom;

(c) Establish and enforce health standards for the protection and the promotion of the public's health such as quality of health services, reporting of disease, regulation of health facilities, environmental health hazards and personnel;

(d) Affect the quality of public health and general health care services by providing consultation and technical training for health professionals and paraprofessionals;

(e) Promote personal health by conducting general health education programs and disseminating health information;

(f) Coordinate and integrate local, state and federal programs and services affecting the public's health;

(g) Continually assess and evaluate the effectiveness and efficiency of health service systems and public health programming efforts in the state; and

(h) Advise the governor and legislature on matters relating to the public's health.

Minnesota Statutes, section 144.072 IMPLEMENTATION OF SOCIAL SECURITY AMENDMENTS OF 1972.

Subdivision 1. **Rules.** The state commissioner of health shall implement by rule, pursuant to the administrative procedures act, those provisions of the social security amendments of 1972 (Public Law Number 92-603) required of state health agencies, including rules which:

(a) establish a plan, consistent with regulations prescribed by the secretary of health, education and welfare, for the review by appropriate professional health personnel, of the appropriateness and quality of care and services furnished to recipients of medical assistance; and

(b) provide for the determination as to whether institutions and agencies meet the requirements for participation in the medical assistance program, and the certification that those requirements, including utilization review, are being met.

Subd. 2. **Existing procedures.** The policies and procedures, including survey forms, reporting forms, and other documents developed by the commissioner of health for the purpose of conducting the inspections of care required under Code of Federal Regulations, title 42, sections 456.600 to 456.614, in effect on March 1, 1984, have the force and effect of law and shall remain in effect and govern inspections of care until June 30, 1987 unless superseded by rules adopted by the commissioner of health.

Minnesota Statutes, section 144.122, subdivision 1, clauses (7) and (11). REGULATION, ENFORCEMENT, LICENSES, FEES.

Subdivision 1. **Rules.** The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health. The rules shall not conflict with the charter or ordinance of a city of the first class upon the same subject. The commissioner may control, by rule, by requiring the taking out of licenses or permits, or by other appropriate means, any of the following matters:

(7) The treatment, in hospitals and elsewhere, of persons suffering from communicable diseases, including all manner of venereal disease and infection, the

disinfection and quarantine of persons and places in case of those disease, and the reporting of sicknesses and deaths from them;

(11) The collection, recording, and reporting of vital statistics by public officers and the furnishing of information to them by physicians, undertakers, and others of births, deaths, causes of death, and other pertinent facts;

III. Procedure for Development and Adoption of Rules.

Notice of Solicitation, additional notice, comment received. In accordance with Minnesota Statutes, section 14.10, the Minnesota Department of Health published a Notice of Solicitation in the *State Register* on July 5, 1994 at 18 S. R. 86 (*State Register*, July 5, 1994). In accordance with statute, a copy of the notice to be published was mailed to all interested parties on the department's certified mailing list (MDH Certificate June 28, 1995; Affidavit of mailing June 28, 1995). A copy of the notice was also mailed to representatives of local boards of health, physicians, the Minnesota Animal Control Association, Board of Animal Health, Minnesota Medical Association, animal interests who had petitioned the department to undertake rulemaking, (DEFFBAM petition, July 1, 1991) and the Legislative Commission to Review Administrative Rules. A copy of the notice was also published in the June/July 1994 Disease Control Newsletter published by the Minnesota Department of Health and distributed to all licensed physicians, all public health agencies, hospitals, and most people affected by the reporting rule (DCN, June 1994).

The department received five written comments as a result of the published Notice of Solicitation on July 5, 1994 - three of which were requests to participate in the rule development process and be included on any mailing list relating to the rule. Comment received from the Notice of Solicitation has been entered into the record.

Previously, on January 13, 1992, in response to a petition on part 4605.7600 submitted under Minnesota Statutes, section 14.09, the department published a Notice of Solicitation in the *State Register* at 16 S.R. 1687 (Vol 16, No 29). Comment received as a result of publication of the notice (Comment) were summarized and several options for revision identified (MDH July 23, 1992 memo). The options were discussed with the State Community Health Services Advisory Committee which adopted rabies and animal control as part of its 1993 and 1994 work plans.

Circulation of draft and description of changes to interested parties. In February of 1995, the department circulated copies of a draft of the rule along with a description of the proposed rule amendments to interested persons including

DEFFBAM and the Minnesota Medical Association. MDH presented the rule draft and description to the Minnesota Emerging Infections Program Technical Advisory Group (EIP) members on February 9, 1995. Comment on the rough draft was requested over a 30 day period.

Publication of proposed rule and notice to adopt, additional notice. In addition to publication of the proposed rules and notice to adopt in the *State Register* and mailing of the proposed rule and notice to all parties on the department's certified mailing list, (Certificate, date; affidavit, date; Notice, date; Proposed rule) the notice and proposed rule and Statement of Need and Reasonableness were also mailed to a discretionary list of interested parties compiled for this rule. This additional mailing and notice included the Minnesota Emerging Infections Program Technical Advisory Group members, local boards of health, physicians, the Minnesota Animal Control Association, the Board of Animal Health, the Minnesota Medical Association, animal interests who had petitioned the department to undertake rulemaking, and the Legislative Commission to Review Administrative Rules.

IV. Fiscal Impact on State and Local Government.

Pursuant to Minnesota Statutes, sections 3.982, 14.11 and 15.065, the Department is compelled to assess the net cost of the proposed rules on state and local public bodies. The proposed rules will not require the expenditure of public monies by state or local public bodies in excess of $100,000 in either of the two years following adoption of these rules. Local boards of health already have authority to control public health nuisances. Minnesota Statutes, section 35.04 DUTY OF LOCAL BOARDS OF HEALTH, has, since 1985, instructed local boards of health to assist the state Board of Animal Health "in the prevention, suppression, control, and eradication of contagious and infectious dangerous diseases among domestic animals...." Local boards of health and other public bodies have been part of the state's disease reporting system for many years. The proposed rules do not significantly add to this existing practice.

V. Small Business Considerations.

Minnesota Statutes, section 14.115 requires that an agency consider five factors for reducing the impact of proposed rules on small business. According to Minnesota Statutes, section 14.115 a small business is an entity, including its affiliates, that (a) is independently owned and operated; (b) is not dominant in its field; and (c) employs fewer than 50 full-time employees or has gross annual sales of less than $4 million. The proposed amendments may impact small businesses such physicians, veterinarians in single or small group practice, and other small health care operations.

The methods delineated in Minnesota Statutes, section 14.115 for reducing the impact of the rule on small business include:

(a) the establishment of less stringent compliance or reporting requirements for small businesses;

(b) the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small business;

(c) the consolidation or simplification of compliance or reporting for small business;

(d) the establishment of performance standards for small businesses to replace design or operational standards required in rule; and

(e) the exemption of small businesses from any or all the requirements of the rule.

The Minnesota Department of Health has considered the five methods for reducing the impact of the rule on small business. The department has determined that there is no direct correlation between the size of the business and the need to protect public health with respect to the reporting requirements specified within the rule. Less stringent compliance, less stringent schedules or deadlines are not relevant with respect to the need for reporting, timely submission of isolates, analysis of samples and action necessary to address a new or emerging threat from communicable or infectious disease. The proposed rules represent an approach that the department believes is the most basic and simple possible for all regulated parties. The independence of the regulated party, its dominance in its field, the number of employees, or gross annual sales is not viewed in health statutes and regulations as the basis for exclusion from public health protection or reporting requirements, particularly in the area of infectious disease control.

VI. Impact on Agricultural Land.

The proposed rules will have no direct or substantial adverse impact on agricultural land.

VII. Rule by Rule Discussion of Need and Reasonableness.

Part 4605.7000 DEFINITIONS.

Subpart 1. **Case.** The proposed amendment to existing subpart 1 of part 4605.7000 is needed to clarify that a "case" is a person who not only may have a disease, but also includes a person who may be "infected with a particular infectious agent." In the case of a person who tests positive with the human immunodeficiency virus or tuberculosis, the individual may or may not exhibit symptoms of a particular disease, but may still have an infectious agent that is communicable.

Subp. 2. **Carrier.** The proposed amendment to existing subpart 2, the definition of "carrier," is necessary to simplify the definition. The phrase "in the absence of a discernible clinical disease" is redundant.

Subp. 4. **Infection control practitioner.** The proposed amendment to existing subpart 2, the definition of "infection control practitioner" is a minor change to bring the term up to date. The health care system contains many different settings for the delivery of care other than "institutions." "Facility" is the term used in part 4605.7030, subpart 2 "health care facilities" encompassing not only hospitals, but nursing homes, medical clinics and other health care settings. The amendment to this subpart is necessary and reasonable because it makes the rules internally consistent and uses the broader term "facility."

Subp. 7. **Medical laboratory.** The proposed amendment to existing subpart 7, the definition of "medical laboratory" is necessary to ensure that "referred cultures of specimens" as well as original specimens are included. Medical laboratories work not only on original specimens but also on cultures from a referring laboratory. It is necessary to include not only original specimens but also the referred cultures from those specimens because the referred cultures may provide needed information to address a communicable disease outbreak in a timely manner.

Subp. 11. **Public health hazard.** The proposed amendment to existing subpart 11, the definition of "public health hazard," is necessary to ensure that infectious agents which may cause disease are reported. The proposed amendment is consistent with the concept that it may be the presence of the infectious agent, rather than the disease, that represents a public health hazard.

Part 4605.7010 PURPOSE.

The minor amendment to this existing rule part is necessary to move the text from the passive to the active voice.

Part 4605.7020 APPLICABILITY.

The proposed amendments to this existing rule part are necessary to delete the unneeded word "generally" and replace "suspect" with "suspected" cases. "Suspected cases" is the defined term in part 4605.7000, subpart 9. It is necessary to use the defined term throughout the rules.

Part 4605.7030 PERSONS REQUIRED TO REPORT DISEASE.

Subp. 2. **Health care facilities.** Most of the proposed amendments to this existing subpart are of a technical nature. "Must" is the preferred term to "shall" by the Office of the

Revisor. It is necessary to change "the" to "all" at line 13 to ensure that all physicians report. The addition of the phrase "the health care facility must" is necessary to ensure that the rule part is clear about what entity has the responsibility to designate a person responsible for reporting to the commissioner.

Subp. 3. **Medical laboratories.** A key element in surveillance is timeliness. Laboratories may work with cultures of original specimens, or the initial culture may be referred to another lab for further tests. To act in an informed and timely manner, the department needs as much information as possible. The modification to this existing subpart is proposed to clarify that the results of "Microbiologic cultures, examinations, immunologic assays for the presence of antigens and antibodies and any other laboratory tests" relating to the diseases and syndromes listed are required for submission. The intent is to be inclusive of results or information relating to the disease or syndrome in question and to recognize the development of new tests. The timeframe of one working day is consistent with the one day reporting requirement specified in part 4605.7050.

The Minnesota Department of health is interested not only in the reporting of positive results by laboratories, but also in the submission of selected bacterial isolates to the Department's Public Health laboratory. The development of molecular subtyping techniques, available only through the Public Health Laboratory, allow for enhanced surveillance by identifying clusters of organisms that may be part of an outbreak. An example is the recent outbreak of *Salmonella enteritidis* associated with the consumption of Schwan's ice cream. This outbreak was recognized because *Salmonella* isolates were submitted to the Public Health Laboratory for serotyping. Molecular subtyping techniques now being used at the Public Health Laboratory will increase the Department's ability to detect similar outbreaks.

Subp. 6. **Others.** The proposed amendment to existing subpart 6 is necessary to ensure that all persons providing health care report suspected cases of the diseases specified in part 4605.7040, not just the physician who "examines" the patient. Health care is provided in settings other than the hospital or physician's office. Providers within the health care system in nursing homes, store front clinics, or in the hospice or home care setting, may have knowledge of the diseases and infectious agents specified in part 4605.7040. It is reasonable that these other health care providers also report to the commissioner.

Part 4605.7040 DISEASE AND REPORTS; ISOLATE SUBMISSIONS.

Item A. The deletion of "Acquired Immune Deficiency Syndrome" is necessary to accommodate addressing this disease in item Z along with human immunodeficiency virus.

Item G. Campylobacteriosis is the most common bacterial diarrhea in Minnesota. Isolates need to be serotyped and further characterized to allow for the detection of outbreaks and the timely development of public health interventions.

Item H. Cat scratch disease is necessary to add as a reportable disease because it is an emerging infection with special risk to immunocompromised hosts.

Item I. Chancroid is proposed as a disease that needs to be immediately reported because of the need to rapidly identify and treat contacts.

Item J. Specific clinical syndromes associated with *Chlamydia* infection are proposed for deletion for simplicity.

Item K. *Vibrio cholerae* isolates need to be further characterized to identify the source and determine whether they are associated with epidemic-strains or are non-toxigenic strains.

Item L. Cryptosporidiosis is necessary to add because it is an emerging infection with significant potential for transmission through contaminated surface water supplies. Surveillance is necessary to evaluate the public health significance of *Cryptosporidium parvum* in water.

Item M. Dengue virus infections are mosquito-borne infections that may occur in travelers to Central and South America and the Caribbean Basin. It is necessary to add because mosquitoes capable of transmitting dengue virus have been imported into Minnesota in used truck tires.

Item N. Diphtheria is a rare infection in the United States, but has recently re-emerged in Russia. Suspected diphtheria isolates need to be characterized to determine their disease causing potential and to identify potential sources of transmission.

Item P. Ehrlichiosis infections needs to be added because infections have recently been reported in Minnesota and Wisconsin. Surveillance for these infections is needed to identify the geographic areas of risk. In August 1993 in the MDH publication Disease Control Newsletter MDH reported that physicians in a Duluth clinic reported the occurrence of human ehrlichiosis in residents of Minnesota and Wisconsin. Ehrlichia are rickettsia-like bacteria that are transmitted through tick bites. Since 1990, nine patients were identified, six residents of Wisconsin; three of Minnesota. One patient died. Reporting of the disease was requested .

Echinococcosis is proposed for deletion from the list of reportable diseases because of its current low incidence and lack of public health intervention.

Item R. Enteric *Escherichia coli* infections are necessary to add as a reportable illness because the infections are a major emerging disease. They are a major cause of diarrheal illness. Isolates need to be further characterized and subtyped to allow for detection of outbreaks through laboratory-based surveillance. In the November/December 1988 issue of MDH Disease Control Newsletter (pages 56 to 61) two outbreaks in Minnesota were reported, one in a junior high school, the other in a day care facilities. This illness, associated with food and most recently with raw or undercooked hamburger, has resulted in death or damage to vital organs. Reporting of cases was requested in 1988.

Item T. Gonorrhea. Examples of clinical manifestations are proposed for deletion to make it clear that all *Neisseria gonorrhea* infections are reportable.

Item U. *Haemophilus influenzae* disease. Examples of clinical manifestations are deleted to make it clear that all invasive disease is reportable. Isolates need to be serotyped and further characterized to evaluate the efficacy of the *Haemophilus influenzae* type B vaccine and to further the Department's understanding of the epidemiology of these infections.

Item V. Hantavirus is an emerging infection that was first reported as a cause of disease in the United States in 1993. The hantavirus pulmonary syndrome outbreak that occurred in the Southwestern United State during 1993 demonstrated the public health significance of this disease. Its transmission through rodent feces is a potential health hazard because the same species of rodents are found in Minnesota. An update on the disease was noted by MDH in 1993 and a request made to inform local or state health authorities of suspected cases.

Item W. Hemolytic uremic syndrome. The commissioner has requested reporting of this syndrome since January 1987 (MDH Disease Control Newsletter, January/February, 1987, page 4). Of 12 case onsets identified in children in Minnesota between May 26 and September 14, 1986, one died, one underwent a total colectomy and eight required transient hemodialysis. In response to the outbreak, MDH requested reporting by health care providers.

Item X. Hepatitis. The proposed rule updates this provision by requiring all primary viral types A, B, C, D, and E rather than A, B, and non-A and non-B.

Herpes simplex infections are proposed for deletion because of the lack of public health intervention.

Item Z. The proposed rule includes acquired immunodeficiency syndrome as a manifestation of human immunodeficiency virus infection.

Item BB. Kawasaki disease has been requested for reporting by the commissioner of health since April 1989 through publication of an article in the MDH Disease Control Newsletter (April 1989, pages 20 and 21.) Several clusters of Kawasaki disease occurred in Minnesota. The disease had been recognized for more than 20 years in Japan and for about 10 years in the U.S. The disease is an acute, febrile, self-limited, exanthematous illness that occurs predominantly in children under age five. The mortality rates in approximately 1-2 percent and generally results from cardiac involvement the American Academy of Pediatrics reported in 1986. Surveillance for Kawasaki disease was requested.

Lead poisoning is proposed for deletion from existing rule because it is not a communicable condition and is reportable through other statutory authority.

Item FF. Listeriosis has been requested for reporting by the commissioner of health since March of 1987. In the March 1987 MDH Disease Control Newsletter the department reported that in August 1986 and in January 1987 the Food and Drug Administration recovered Listeria monocytogenes from samples of ice cream sold in Minnesota. The identification resulted in the voluntary recall of more than one million gallons of ice cream. Six cases were reported. L. monocytogenes causes meningitis, septicemia, and neonatal mortality. It has also recently been recognized to cause spontaneous abortion, stillbirth, and premature labor. During an outbreak reported by CDC in 1985 13 stillbirths and 45 cases of neonatal disease were reported among 86 cases. MDH established a statewide active surveillance system for L. monocytogenes as a response to the outbreaks and requested the submission of isolates.

Item HH. The proposed rule simplifies the reporting request for Malaria to include all *Plasmodium* species.

Item JJ. Meningitis. The proposed rule specifies reporting of meningitis cause by specific bacterial pathogens and all viral meningitis. Fungal meningitis is proposed for deletion because of the lack of public health intervention. Isolates need to be serotyped and further characterized to allow detection of outbreaks and the rapid development of public health interventions.

Item KK. Meningococcemia. Isolates need to be serotyped and further characterized to allow detection of outbreaks and the timely development of public health interventions.

Item LL. Mycobacteriosis other than tuberculosis and leprosy are deleted because of confusion between carriage and infection and because of the lack of public health intervention.

Item MM. Pertussis is proposed as a disease that needs to be immediately reported. Isolates need to be submitted for Pertussis to help characterize the epidemiology of pertussis transmission in the community.

Item SS. Retrovirus infectious (other than HIV) have been requested for reporting by the commissioner of health since January 1989 when MDH published the article "Surveillance for Retrovirus Infections in Minnesota," in the MDH Disease Control Newsletter (January/February 1989, page 6).

Item XX. Isolates need to be serotyped and further characterized to allow detection of outbreaks and the timely development of public health interventions.

Item YY. Isolates need to be serotyped and further characterized to allow detection of outbreaks and the timely development of public health interventions.

Outbreaks of staphylococcal disease are proposed for deletion because foodborne illness outbreaks are separately reported.

Item ZZ. The proposed rule would require reporting of all invasive streptococcal infections caused by groups A and B streptococci and *S, pneumoniae*. Isolates need to be serotyped and further characterized to help define the epidemiology of the disease.

Item CCC. Isolates need to be serotyped and further characterized to allow for the detection of outbreaks and the timely development of public health interventions.

Item DDD. Toxoplasmosis is a disease of special concern to pregnant women and immunosuppressed individuals. Reporting is needed to evaluate rates of transmission and the risk of acquiring infection.

Item FFF. Tuberculosis isolates need to be serotyped and further characterized to allow for the detection of outbreaks and the timely development of public health interventions.

Item HHH. The proposed rule is simplified to include the reporting of all Typhus *Rickettsia* species.

Item JJJ. Yersiniosis isolates need to be serotyped and further characterized to allow for the detection of outbreaks and the timely development of public health interventions.

Part 4605.7050 UNUSUAL CASE INCIDENCE.

This existing rule part remains necessary to allow the commissioner to respond to new and emerging diseases and syndromes. Diseases and disease-causing agents are evolving. Because of the global nature of our food supply and easy access to fast transportation, disease and infectious agents are not confined to a locality, countries or even continents. This provision is designed to require reporting of "newly recognized infectious agents."

The CDC in the 1994 publication "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States" notes in the preface:

> The spectrum of infectious disease is changing rapidly in conjunction with dramatic changes in our society and environments. Worldwide, there is explosive population growth with expanding poverty and urban migration; international travel is increasing; and technology is rapidly changing -- all of which affect our risk of exposure to the infectious agents with which we share our environment. Despite historical predictions to the contrary, we remain vulnerable to a wide array of new and resurgent infectious diseases.
>
> Our vulnerability to emerging infections was dramatically demonstrated in 1993. A once obscure intestinal parasite, *Cryptosporidium*, caused the largest waterborne disease outbreak ever recognized in this country; an emerging bacterial pathogen, *Escherichia coli* O157:H7, caused a multi-state foodborne outbreak of severe bloody diarrhea and kidney failure; and a previously unknown hantavirus, producing an often fatal lung infection, was linked to exposure to infected rodents.
>
> In recent years, our antimicrobial drugs have become less effective against many infectious agents and experts in infectious diseases are concerned about the possibility of a "post-antibiotic era."

The duty to report is not limited to an attending physician. This rule part is amended to require reporting by medical examiners, coroners and by a person with knowledge about the death. These other persons may discern, in the course of care, examination, or autopsy, that the cause of death or illness is unusual or can not be readily explained. To protect public health in situations such as the recent hantavirus outbreak, it is necessary to rapidly learn of new and emerging infectious agents, diseases and syndromes so the public and health care community can be alerted and the public health protected.

A one day reporting timeframe is consistent with the reporting time period specified in part 4605.7020 subparts 2, 3, and 6.

Part 4605.7060 CASES, SUSPECTED CASES, CARRIERS, AND DEATHS DUE TO DISEASE ACQUIRED OUTSIDE THE STATE.

The amendment deleting "viral, bacterial, fungal, or parasitic" and replacing this phrase with "infectious" agent is necessary to simplify the proposed rule. The addition of the term "geographic" as a modifier to "area" is needed to clarify that it is the place on earth where the agent was allegedly acquired that needs to be known, not the place on the human body.

Part 4605.7075 TUBERCULOSIS; SPECIAL REPORTING.

This new rule part is necessary to allow the commissioner of health to respond in a timely manner to the public health threat presented by an individual with active pulmonary tuberculosis who refuses tuberculosis treatment or is noncompliant with prescribed therapy for tuberculosis.

The term "noncompliant" means that the patient is not taking medications as prescribed or not following the recommendations of the attending physician or health officer for the management of tuberculosis. A patient is considered unable to unwilling to comply with prescribed treatment if the patient does not report for medical visits or for directly observed therapy, refuses medications or shows other evidence of not taking medications as prescribed such as incorrect pill counts or urine tests showing no evidence of drug metabolites.

Pulmonary tuberculosis is a disease that is spread person-to-person through droplet muclei discharged into the air from a case of active disease. The major cornerstone of tuberculosis prevention programs is to identify active cases of pulmonary tuberculosis and assure that each active case completes a course of treatment. A person with active pulmonary tuberculosis who refuses to complete a course of treatment poses a potential health risk (either because the person is still infectious or may become infectious at a later date due to inadequate treatment). When a person with active pulmonary tuberculosis is noncompliant with therapy, public health officials can take steps to assure that therapy is completed. It is essential for physicians to report those patients who refuse treatment or who do not comply with treatment so action to protect the public health can be taken.

Part 4605.7080 NEW DISEASES AND SYNDROMES.

The proposed amendments to existing part 4605.7080 simplify the criteria by which the commissioner requires the reporting of newly recognized or emerging diseases and syndromes. Isolates

need to be submitted to identify and further characterize the infectious agent and help define the epidemiology of the disease.

Part 4605.7090 DISEASE REPORT INFORMATION.

The proposed amendments to this existing part add requirements to report primary signs and symptoms.

Item A is amended to add the term "carrier." This is necessary because carrier is defined and it is appropriate to consistently use defined terms throughout the rules.

Item C "primary signs and symptoms" is added to require that primary signs and symptoms also be reported. Knowing the primary signs and symptoms is essential to properly address an outbreak in a timely manner. For example, *Salmonella* may be diarrheal or extra intestinal. Knowing the signs and symptoms of the disease helps the department make a preliminary assessment of the nature of the illness and determine what needs to be done to address it.

Item D, subitem (4) is modified to add the requirement that information reporting include the case's zip code. This amendment is necessary to facilitate the computerized processing of outbreaks as they develop.

A minor amendment is proposed to Item D, subitem (6). Within the child care field, the term "child care" is used when describing the broad array of services and facilities providing care to children. Such care may include facilities providing night care, drop in centers, and sick care centers. Minnesota Rules, chapter 9503 governs the "licensure of child care centers."

Part 4605.7700 SEXUALLY TRANSMITTED DISEASE CONTROL; SPECIAL REPORTS.

The proposed amendments to adopted parts 4605.7700 and 4605.7800 update language relating to sexually transmitted disease, extend special reporting requirements to *Chlamydia trachomatis*, and allow the commissioner of health to authorize specific outpatient or inpatient facilities to report specific sexually transmitted diseases and clinical syndromes in addition to those specified in part 4605.7040.

Chlamydia trachomatis infection has been added to existing Items A, B and C. This infection is added to the list of special reports that must be provided to the commissioner whenever an infected person has not received treatment. The Minnesota Department of Health provides follow-up to ensure that all patients with reportable sexually transmitted diseases receive appropriate treatment to prevent further transmission. The previous language specified only gonorrhea, syphilis and

chancroid for special reporting of untreated cases. Chlamydia infection is added because it has been a reportable disease since 1985 and is curable with antibiotic therapy.

The additional language proposed for item B is necessary to clearly indicate that physicians are responsible for providing preventive treatment to sexual partners of persons with *Chlamydia trachomatis*, syphilis, gonorrhea, or chancroid. The Centers for Disease Control and Prevention recommends that sexual contacts be treated regardless of test results and that physicians have a responsibility to provide treatment for both the patients and the patient's partner. Treatment of partners is important to prevent reinfection of the original patient and further transmission to others. Physicians who do not provide treatment for partners have an obligation to provide partner names and locating information to the commissioner so that public health personnel can initiate follow-up for treatment.

Language is added to indicate that persons known to be sexual or needle-sharing contacts of persons with human immunodeficiency virus infection must be reported to the commissioner. The Minnesota Department of Health provides partner notification services for these individuals who may not be aware of their risk for human immunodeficiency virus infection. Evaluation data support the benefit of provider referral and demonstrate that positive behavior change occurs when at-risk persons are notified.

The proposed amendment to Item C is added to provide complete and useful public health data on the prevalence of different sexually transmitted diseases and their complications. Sexually transmitted diseases such as chlamydia infection and gonorrhea are important because they cause severe reproductive complications, including pelvic inflammatory disease and ectopic pregnancy. It would be difficult to assess the prevalence of these complications only with statewide reporting by all physicians. Unlike gonorrhea or chlamydia infection, the complications resulting from sexually transmitted diseases cannot be ascertained through laboratory reporting. Statewide reporting by physicians would be biased by under reporting and lack of standardized case ascertainment.

Item D authorizes selected facilities to report cases of sexually transmitted disease syndromes and their reproductive complications. These facilities would function as "sentinel clinics" where uniform screening criteria and case definitions would be used to ascertain cases. The data from these facilities will then be used to calculate the prevalence of sexually transmitted disease syndromes and their complications. This "sentinel clinic" system will provide accurate and useful information without requiring statewide reporting of sexually transmitted disease syndromes and complications.

Part 4605.7800 HEALTH EDUCATION.

The information required by this existing rule is being updated to include chlamydia trachomatis infection. It also states that patients must be informed about the need to have sexual contacts treated (rather than just examined) for the specific disease. The amendment is necessary because guidelines from the Centers for Disease Control and Prevention emphasize that partners should be treated even if examination is not possible (CDC Guideline, date).

REPEALER.

Part 4605.7600 RABIES is proposed for repeal. The commissioner of health's role in the evaluation of animal bite situations is limited to reviewing factual data about the bite and making recommendations on observing or testing the animal or treating the individual who was bitten. The control of nuisance and biting animals lies with local health authorities, local animal control officers and public safety officials. The Minnesota Animal Control Association in "An Animal Control Officer's Guide to Minnesota Animal Laws," points out that Minnesota Statutes, chapter 346 addresses stray, companion animals and pets. Section 346.51 specifically addresses animal bites (MACA).

Parts 4605.7701 to 4605.7715 regarding the operation of community venereal disease control clinics are proposed for repeal. The rules contain nonregulatory language and are obsolete.

State of Minnesota
Minnesota Department of Health

In the Matter of Proposed Permanent Rules Relating to Health, Disease and Syndrome Reporting, Minnesota Rules, parts 4605.7000 to 4605.7800

Statement of Need and Reasonableness

Date: May 25, 1995

Anne Barry
Acting Commissioner of Health

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