

STATEMENT OF NEED AND REASONABLENESS (SONAR)

COMMUNICABLE DISEASE REPORTING RULE

MINNESOTA DEPARTMENT OF HEALTH

February 1, 2011

MINNESOTA DEPARTMENT OF HEALTH

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MINNESOTA DEPARTMENT OF HEALTH

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Proposed Amendment to Rules Governing Minnesota Communicable Disease, Minnesota Rules Part 4605.7030.

Note: A glossary of terms can be found in Attachment A.

I. INTRODUCTION

The Minnesota Department of Health (MDH) proposes to amend one part of the current Communicable Disease Reporting Rules, specifically Minnesota Rules, part 4605.7030. The communicable disease rules form the backbone of MDH's ability to monitor and control communicable disease in Minnesota. Under the rules mandated reporters notify MDH of cases, suspected cases, and carriers. They also report deaths from communicable diseases and conditions of public health significance. Medical laboratories submit clinical materials under the rules that the MDH Public Health Laboratory (MDH PHL) tests to identify or confirm the disease-causing agent and, potentially, link cases of disease to a common source.

MDH thoroughly revised the current rules in 2005. Since then, testing technology for Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) has evolved from using a screening test and confirming with Western Blot to rapid testing often without a confirmatory Western Blot. Rapid testing is now in almost universal use. The laboratory-reporting rules must be brought up to date to keep pace with current standards.

Current technology allows for labs to use an HIV rapid test, which is a blood test that detects antibodies to HIV in the screened person. This test is performed at the point-of-care and results are available within 10 to 20 minutes. If antibodies are detected, the person is HIV-positive. The labs confirm this rapid test with a viral detection test in lieu of the out-moded Western Blot test, which measures the immune response to the virus.¹ The current rules do not specify that labs submit all results of viral detection tests to MDH, and they should.

Since the rules are not precise, we have inconsistent reporting results with some laboratories interpreting the rules to allow submission of all viral detection tests, which includes reporting of undetectable viral loads, while other laboratories only report tests that detect virus in the blood. Having an undetectable viral load means that the test is not sensitive enough to detect the virus in the person, but the person is still HIV positive. With the advent of better drugs for the control of HIV, more and more people are living with undetectable viral loads. It is important that cases who have undetectable viral loads be reported so that MDH can get an accurate count of people living with HIV in Minnesota for prevention and care planning purposes. Consequently, current rules are simply inadequate.

MDH's proposed amendments reflect current national laboratory reporting practice for HIV/AIDS and foster a stronger, more flexible public health system, a system that is

¹ A Western Blot Complete test is a laboratory test used to detect specific proteins in a tissue sample, such as blood. This test looks for HIV antibodies and can confirm if a person is infected with the HIV virus

equipped to respond to known HIV/AIDS disease information. Further, the proposed amendments reflect a new climate created by the privacy standards that the federal Health Insurance Portability and Accountability Act (HIPAA)² provides. In this new climate, reporters of communicable disease increasingly want explicit provisions on reporting to ensure they are protected when they provide health information to MDH. Revision of the rules is critical for MDH to continue to:

- conduct effective surveillance³ and disease investigation, identify outbreaks, and promptly respond to newly diagnosed cases;
- implement outbreak control measures to stop the spread of HIV/AIDS; and,
- keep Minnesotans healthy both medically and economically.

MDH began work on potential rules revisions in fall 2009. The agency published a Request for Comments in the State Register on January 1, 2010 with a closing date of March 15, 2010. MDH notified affected parties of the Request for Comments through multiple means. (See Attachment B for efforts MDH used to notify affected parties.)

II. ALTERNATIVE FORMAT REQUEST

Upon request, this SONAR can be made available in an alternative formats, such as large print, Braille, CD, or audio. To make a request, contact Patricia Segal Freeman, Minnesota Department of Health, 625 Robert Street N., P.O. Box 64975, St. Paul, MN 55164-0975: (651) 201-5414, 1-877-676-5414, FAX (651) 201-5666 or health.hivlabrule@state.mn.us. TTY users may call the Minnesota Department of Health at (651) 201-5797.

III. STATUTORY AUTHORITY FOR MODIFYING THE RULES

MDH's statutory authority to amend the rules is stated in Minnesota Statutes:

- A. Minnesota Statutes, section 144.12, subdivision 1, states: "The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health."
- B. Minnesota Statutes, section 144.05, subdivision 1, establishes the general duties of the commissioner of health (commissioner). Under Minnesota Statutes, section 144.05, subdivision 1, paragraph (a), the commissioner is authorized to "conduct... investigations," to "collect and analyze health...data," and to "identify and describe health problems." Further, Minnesota Statutes, section 144.05, subdivision 1, paragraph (c), authorizes the commissioner to "[e]stablish and enforce health standards for...reporting of disease."

Minnesota Statutes, section 144.05, subdivision 1, states:

Subdivision 1. **General duties.** 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. This authority shall include but not be limited to the following:

² Among other requirements, HIPAA creates federal standards for the privacy of health information.

³ This term has been defined as "the continuing scrutiny of all aspects of occurrence and spread of a disease that are pertinent to effective control." Last, John M; A Dictionary of Epidemiology, Oxford Medical Publications, (1983).

- 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.

Under these statutes, MDH has the necessary statutory authority to amend the rules. This rulemaking amends existing rules that have been amended since 1995. Previous rulemaking satisfied the requirements of *Minnesota Statutes*, section 14.125, so the Department retains its rulemaking authority.

IV. REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, lists seven factors for regulatory analysis that state agencies must include in a SONAR. Paragraphs (A) through (G), that follow, quote these factors and MDH's response to them. Section VI of the SONAR, the Rule-by-Rule Analysis, also addresses some of these factors.

A. A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

1. Classes of Persons Affected by the Proposed Rule

The existing rules apply to persons and entities required to report communicable diseases and conditions. The proposed rule amendments do not change who is required to report, but clarify who must report certain test results. These changes, clarifying for labs who and what must be reported, affect the following persons and entities:

- Medical laboratories required to report test results and submit clinical materials on reportable diseases and conditions
- The general public and all visitors to the state who acquire a reportable disease or condition, or who come in contact with a person who has a reportable disease or condition
- Minnesota Department of Health

2. Classes of Persons Who Will Bear the Costs of the Proposed Rule

- Clinical Laboratories who perform HIV viral detection and CD4+ lymphocyte count and percent tests.
- Minnesota Department of Health

3. Classes of Persons Who Will Benefit from the Proposed Rule

- Minnesota Residents and Visitors: The beneficiaries of the proposed rules include every child, adolescent, and adult who lives in Minnesota, and all visitors to the state. Minnesota citizens and visitors benefit because MDH's communicable disease reporting system will reflect new laboratory methods, thereby maintaining the agency's ability to properly investigate and control communicable disease in the state. It is through reporting and investigation that MDH is able to implement control measures to protect the public.
- Mandated Reporters: Mandated reporters also will benefit from updated rules. First, as a result of a strong surveillance system, MDH can quickly alert health care providers about communicable diseases of concern and disseminate guidelines on infection control precautions (to protect hospital and clinic staff), diagnosis, and treatment. Second, when individual health care providers or facilities are faced with communicable diseases for which diagnosis, treatment, or infection control precautions are not straightforward, MDH assists with communicable disease expertise through a staff of clinicians and epidemiologists. MDH also facilitates assistance from the federal Centers for

Disease Prevention and Control (“CDC”). Third, by specifically stating what results are reportable in the rule, mandated reporters will not be concerned with HIPAA violations. Fourth, MDH disseminates aggregate information obtained under the rules in a manner that can assist clinicians in their practice.

- Minnesota HIV-positive community: A strong surveillance system for HIV/AIDS will ensure that MDH has updated and accurate information on the number of people diagnosed and living with HIV/AIDS in Minnesota to provide to the federal agencies that utilize these figures to determine the amount of funding Minnesota receives to provide HIV prevention and care services. In addition, a system that truly reflects the epidemiology of HIV/AIDS in Minnesota will provide better information for those working with the HIV-positive community that can be used for service planning and development.

B. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

1. Probable costs to the agency of implementation and enforcement

The probable costs to MDH for implementing the proposed rule amendment will be minimal. Existing agency staff will be able to handle reports on the test results because staff is already assigned to follow-up on HIV/AIDS laboratory results and systems are already in place to receive results electronically. There will be one-time costs associated with the development and distribution of educational materials on the new rules to mandated reporters. To the extent possible, MDH will incorporate these educational materials into MDH’s regular communication channels such as Bug Bytes (an MDH electronic publication). In addition, the MDH Public Health Laboratory (PHL) will notify laboratories on the changes to the rules through an existing listserv.

2. Probable costs to any other agency of implementation and enforcement

There should be no cost to any other state agency or to local public health agencies. MDH will receive all the test results requested.

3. Anticipated effect on state revenues

The proposed rule amendments will not affect state revenues.

C. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

MDH has proposed the least costly and least intrusive methods necessary for achieving the purpose of the rule, namely reporting of communicable diseases and other relevant information for disease surveillance, investigation, and control. (This factor also is discussed in the performance-based standard section on page 9 and the Rule-by-Rule Analysis.)

1. Less costly methods

MDH is not aware of a less costly method to achieve the desired results. The only less costly method would be to make no revision to the rules. However, this would

not achieve the purpose of the amendments, namely ensuring that all cases of HIV/AIDS are reported to MDH so that the agency can take timely action to protect the public and prevent unnecessary illness and death and get an accurate count of all HIV-positive persons in Minnesota. The proposed amendment is discussed in the SONAR in the Rule-by-Rule Analysis.

MDH has concluded that no less costly methods are available to accomplish the purpose of the rules and that the proposed amendment is necessary and reasonable.

2. Less intrusive methods

The two general categories of persons affected by the proposed amendments are laboratories, which are mandated reporters, and persons whose health information is reported. Laboratory facilities that will be mandated to report the information did not raise any issues of intrusiveness during the comment period and many laboratories around the country are already submitting these test results because many other states require it.

As to the added persons whose health information will be reported, the proposed amendments could be viewed as intrusive because they require reporting of otherwise private health information. HIV and AIDS, however, are already reportable diseases in Minnesota. MDH discussed the proposed amendment with Lorraine Teel, Executive Director, Minnesota AIDS Project (MAP) and with Bob Tracy, an HIV/AIDS community advocate. Both are familiar with the HIV-positive community and neither raised issues as to the intrusiveness of the proposed rules. MDH received no comments from the general public after the Request for Comments was published.

Justification for the proposed amendment is in the Rule-by-Rule Analysis. More generally, we know of no method other than reporting of private health information for conducting public health surveillance, investigation, and control of communicable diseases. If MDH only were tracking disease trends, one could argue that a less intrusive method might be to require reporting of de-identified health information (health information without name, address, and other information that could identify the person). However, MDH monitors disease to contain spread and limit illness or death in real time. Identifying information is necessary for MDH to conduct case interviews and determine the most likely source of infection. Further, by interviewing case-patients, MDH is able to identify their family members and other contacts who might be at risk of disease. MDH can then make recommendations to seek medical attention, obtain prophylaxis (use of drug therapy to prevent disease), or take infection control precautions when appropriate.

A recent example demonstrates the critical importance of individual-identifying information. A clinic diagnosed an individual with HIV infection in 2009 through a rapid test followed by a viral detection test but the laboratory is one that does not report viral detection results. As a result, MDH did not receive this person's information until 2010, when a new clinical provider performed a Western Blot test and reported it to MDH. Consequently, the initial viral detection test's not being reported delayed the investigation and prevention and control measures almost a year, losing valuable time.

Further, reporting identifiable health information under communicable disease reporting requirements is the standard and accepted method of surveillance. In fact, federal rules adopted under HIPAA, which set national standards for the privacy of health information, contain an express exemption that permits reporting private health information to health departments authorized by law to receive such information for surveillance.⁴ Under the Minnesota Government Data Practices Act, (Minnesota Statutes, Chapter 13) health data on individuals is private and MDH only can release such data under Minnesota Statutes, sections 13.04 (release to the subject of the data) and 13.3805 (release for certain public health purposes). MDH has an excellent record of maintaining data privacy.

MDH has concluded that no less intrusive methods are available to accomplish the goals of the rules and that the proposed amendments for reporting viral loads are necessary and reasonable.

D. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

Communicable disease reporting requirements are the standard method for performing surveillance for public health purposes in every state in the United States. In addition, MDH's proposed amendment updates the communicable disease reporting rules to reflect current national reporting practice for HIV/AIDS and help ensure a stronger, more flexible public health system that is equipped to respond to known HIV/AIDS disease information. For discussions on alternative methods considered, see the following areas listed below.

1. This SONAR discusses both less costly and less intrusive methods (see factor C above).
2. The only alternative method to achieve the purpose of the proposed amendments would be medical chart reviews at every facility that cares for HIV-positive people. This method would be much more labor intensive, costly, and intrusive because someone would have to review every HIV-positive patient's file. In addition, this would add unnecessary intrusion by allowing reviewers access to information not pertinent to the HIV status.

E. The probable costs of complying with the proposed rule, including the portion of the total costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

1. Probable costs of complying with the proposed rule

⁴ 45 Code of Federal Regulations, §164.512 of the HIPAA regulations addresses "uses and disclosures for which an authorization or opportunity to agree or object is not required." Under §164.512 (b)(1)(i), entities covered by HIPAA may disclose protected health information for public health purposes to:

"a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability including, but not limited to the reporting of disease...the conduct of public health surveillance, public health investigations, and public health interventions..."

Most laboratories that conduct these tests are already reporting the results to other states. Their workload will increase little but the increase should not be substantial for any one reporter. MDH staff are available to assist laboratories if necessary. The agency did not receive any comments from laboratories who were worried about added staff time or costs.

The number of reports received by MDH might increase by approximately 25 to 45 percent. For the laboratories, it should not add to the workload, as most places have automated these reports and it is simply a matter of adjusting their systems to pull out additional results. A few laboratories report on paper but MDH is working with those laboratories to automate their systems.

In written comments to MDH, laboratories felt that making the rules clearer would make it easier to determine what to send to MDH.

2. The portion of the costs borne by identifiable categories of affected parties
 - Laboratories: Under regulatory analysis factor A, MDH listed the categories of affected parties. MDH anticipates that the largest portion of additional cost will be borne by medical laboratories. This cost, however, should be relatively small as mentioned in E(1) above.
 - Government Entities: MDH is the government entity affected by any additional costs under the proposed rules. We anticipate that costs for MDH will be minimal. This is discussed under factor B of the regulatory analysis.

F. The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

1. Probable costs of not adopting the proposed rules

There are significant costs to not going forward with the proposed amendment to the rules. If the rule does not go forward, the State will not have an accurate count of persons living in Minnesota with HIV/AIDS. Not only will this hurt prevention and education efforts, but it also affects the amount of federal money the state receives. The state receives federal funds through the Ryan White Program⁵ and state funds for surveillance and prevention of HIV/AIDS to help reduce the spread of the disease. Disbursement of federal funds is based on the number of cases reported in a state. Therefore, it is critical that the state have an accurate case count. By not having this data reported on a regular basis, the number of persons living with HIV infection is underreported.

2. Portion of costs borne by identifiable categories of affected parties

Under factor A of the regulatory analysis, MDH discussed the parties who would benefit from the rule and how they would benefit.

⁵ The federal Ryan White funds are used to provide medical care, insurance, medication, and support for those living with HIV and AIDS. The funds are administered by the Minnesota Department of Human Services and Hennepin County.

- **Minnesota Residents and Visitors:** The primary beneficiaries of the proposed rules are every child, adolescent, and adult who lives in Minnesota, and all visitors to the state. These same persons would bear the greatest portion of the health (sickness and death) and economic costs associated with not adopting rules to achieve an updated system of communicable disease surveillance, investigation, and control.
- **Mandated Reporters:** The discussion under factor A reflects how mandated reporters would benefit from an updated rule. When MDH has timely information on communicable disease in the state, it can quickly alert health care providers and disseminate guidelines on infection control precautions (to protect hospital and clinic staff), diagnosis, and treatment. Without an updated reporting rule, especially in the wake of HIPAA and reporters wanting explicit legal permission to report, health care providers may bear the costs of MDH not knowing about a communicable disease event.
- **HIV-positive community:** The HIV-positive community would be a beneficiary of the proposed rule and at the same time would bear the greatest cost of not adopting the rule. Funds for care of those living with HIV are assigned to states based on HIV Surveillance numbers, and by not having an accurate count the State of Minnesota may lose funds which would impact the services available to those living with HIV and AIDS.

G. An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

There are no federal regulations regarding communicable disease reporting. This is a state function.

V. ADDITIONAL STATUTORY REQUIREMENTS

A. PERFORMANCE-BASED RULES

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how MDH, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting MDH's regulatory objectives and maximum flexibility for the regulated party and MDH in meeting those goals.

MDH staff discussed performance-based standards by looking at the following three questions to assist them in the discussion.

1. Are there special situations we should consider in developing the rules?
2. Are there ways to reduce the burdens of the rules?
3. Do you have any other insights on how to improve the rules?

Staff discussed the different methods of reporting currently available. This change will be less burdensome for electronic reporters. Even those that report on paper, however, should not see a huge increase in workloads. In fact, one of the laboratories that reports on paper commended MDH for making these changes. They recognized that this

change will make the rule clearer. In addition, MDH is working on expanding electronic reporting and is working with those laboratories that do not currently have it. This will make it even easier for them to report and be less burdensome.

B. ADDITIONAL NOTICE

Minnesota law (Minnesota Statutes, sections 14.131 and 14.23) requires that the SONAR contain a description of MDH's efforts to provide additional notice to persons who may be affected by the proposed amendments to the rules.

MDH submitted an additional notice plan to the Office of Administrative Hearings, which reviewed and approved it on January 26, 2011 by Administrative Law Judge Lews.

The additional notice plan consists of the following steps:

1. Mailing the proposed rules and the dual notice to all persons who have registered to be on MDH's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.
2. Posting the proposed rules, the dual notice, the SONAR, on MDH's Communicable Disease Rule web site at www.health.state.mn.us/divs/idepc/diseases/hiv/hivreportingrule.html and at the MDH HIV web site at www.health.state.mn.us/HIV
3. Providing a copy of the dual notice, the SONAR, and a web link to the proposed rules via e-mail, directly or through a listserv, to various individuals, groups and organizations. MDH will also request, when possible, that these organizations post the information on their website and send it out to their listserv. This list includes, but is not limited to:
 - Health care providers responsible for reporting and health care facilities whose personnel must report communicable diseases and conditions
 - Infectious disease physicians through the North Central Chapter of the Infectious Disease Society of America listserv
 - MDH's infection control practitioner list
 - Minnesota Council of Health Plans
 - Minnesota Hospital Association
 - Minnesota Medical Association
 - Minnesota Nurses Association
 - Local public health agencies through the MDH listserv
 - Medical laboratories
 - MDH's Minnesota Laboratory System list. This list includes approximately 160 laboratories, including public health and private clinical laboratories, as well as veterinary and agriculture laboratories, which serve Minnesota residents.
 - Minnesota Interlaboratory Microbiology Association
 - Organizations that receive funding from the Ryan White Grant and other AIDS/HIV Organizations. Such as:

- DHS and Hennepin County Ryan White Grantees
 - Minnesota HIV Planning Council
 - Minnesota Community Cooperative Council on HIV/AIDS Prevention
 - Fifteen MDH HIV/AIDS Prevention grantees
 - MDH mailing lists of organization and individuals involved in HIV prevention and control, which contain over 100 email addresses. These organizations and individuals have also agreed to pass the information on to others.
 - Minnesota Aids Project (MAP)
4. Notifying the Minnesota Legislature per Minnesota Statutes, section 14.116 and Minnesota Statutes, sections 121A.15, subdivision 12(2)(b) and 135A.14, subdivision 7(d). This will include sending the proposed rules, SONAR, dual notice, and summary of substantive amendments to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

C. CONSULTATION WITH THE MINNESOTA DEPARTMENT OF FINANCE ON LOCAL GOVERNMENT IMPACT

Minnesota Statutes, section 14.131, requires agencies to consult with the Department of Finance to help evaluate the fiscal impact and benefits of the proposed rules on local governments. MDH delivered a copy of the proposed rules and SONAR to the Executive Budget Officer (EBO) for the agency on October 15, 2010.

MDH does not anticipate costs to local agencies as a result of the proposed rules (see section B.2. of the Regulatory Analysis). Local jurisdictions will benefit from an updated system of communicable disease surveillance, investigation, and control. This is because they can help to better protect residents in their jurisdiction when disease outbreaks are detected early.

D. COST DETERMINATION

As required by Minnesota Statutes, section 14.127, MDH has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed \$25,000 for any small business or small city. The reporting labs are privately owned entities and are not under any small cities' jurisdiction. Moreover, as stated on pages 7-8, most of the labs are already performing these tests so the cost of supplying the requested information to MDH is negligible. Therefore, MDH has determined that the rules will not exceed \$25,000 for any small business or small city.

E. SECTION 14.128 ANALYSIS

The Department has considered the requirements of Minnesota Statutes, section 14.128, which requires that “an agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule,” Subdivision 1. These rules amend a regulatory framework for the Department’s duties for communicable disease reporting. All regulatory functions are performed within the Department of Health and do not require local government involvement or enforcement.

Furthermore, the affected parties, which are laboratories, are privately owned entities so the rule does not affect or require local governments to adopt or amend any ordinance or any other regulation.

F. LIST OF NON-AGENCY WITNESSES

If the rules go to a public hearing, MDH anticipates having the following non-agency witnesses testify in support of the need for and reasonableness of the proposed amendments to the rules:

1. Dave Rompa, Minnesota Department of Human Services
2. Jonathan Hanft, Hennepin County
3. Bob Tracy, Public Affairs Consultant/HIV community Advocate

VI. RULE-BY-RULE ANALYSIS

MDH proposes the following amendments to the Communicable Disease Reporting Rules, Minnesota Rules, chapter 4605. MDH has concluded, after careful consideration, that each amendment is reasonable and necessary to further the goals of the rules.

PART 4605.7030 PERSONS REQUIRED TO REPORT DISEASE.

4605.7030, Subpart 3. Medical laboratories. This subpart has two amendments.

The first amendment requires all laboratories to report to the Minnesota Department of Health the results of all CD4+ lymphocyte counts and percents and the results of all HIV viral detection laboratory tests.

To test for HIV/AIDS a health care provider will often order a rapid test.⁶ If the rapid test is positive for HIV, the provider must verify the person is HIV-positive by getting a confirmatory test. While current medical practice is for clinics to confirm with a Western Blot Complete test,⁷ some clinicians are bypassing that step and instead ordering an HIV viral detection test, such as an HIV-1 PCR (polymerase chain reaction) test.⁸ The viral detection test is a better test than the Western Blot test because it is more sensitive, especially for newly infected persons. Using a viral detection test is especially common if the patient’s medical

⁶ A rapid test is a blood test that detects antibodies to HIV in the screened person.

⁷ A Western Blot Complete test is a laboratory test used to detect specific proteins in a tissue sample, such as blood. This test looks for HIV antibodies and can confirm if a person is infected with the HIV virus

⁸ A viral detection test, such as an HIV-1 PCR test, looks for HIV-1 DNA in the white blood cells of a person, whereas the HIV antibody ELISA and HIV antibody Western blot assays measure the immune response to the virus.

records indicate that he or she was identified as positive in a different state or if the clinic is using rapid test technology during an office visit. When the Western Blot, which is clearly reportable by MDH rules, is bypassed for the PCR test, the HIV case may or may not be reported. In fact, an MDH analysis found MDH is not receiving reports of all HIV-Positive people living in Minnesota.

This results in two problems. First, it is crucial that all cases of HIV/AIDS are reported for prevention and control purposes to stop the spread of HIV/AIDS. Second, because the federal government uses HIV/AIDS Surveillance data to determine what the state receives for both prevention and services for HIV/AIDS, an incomplete surveillance system results in less money coming to the state for these purposes.

Given this problem, MDH is proposing language that will clearly state that laboratories, regardless of reporting by clinical providers, must report all viral detection test results, whether HIV is detected or not, as well as all CD4+ counts and percents. The HIV-viral-load detection test lets health care providers know how much HIV virus is in the body. It is important that laboratories report all viral detection tests, even those that are undetectable because with the current available medications for treating HIV/AIDS many of those individuals living with HIV have undetectable viral loads. An undetectable viral load does not mean that there is no virus in your blood; it just means that the test is not sensitive enough to detect the virus in the person. Reporting all viral load results is especially important to ensure that individuals diagnosed in a different state that are now residing in or receiving care in Minnesota are reported to MDH so that an accurate count is available for prevention and care services planning.

In addition to reporting all viral detection test results, MDH needs the results of all CD4+ lymphocyte counts and percents. This is a blood test that measures the strength of your immune system. People who are HIV-positive have compromised immune systems so they often have lower CD4 count than uninfected people. This test is also given to some cancer patients to measure their immune system. As a result, MDH may receive some test results for cancer patients. These results, however, will be shredded and no information will be kept on them. When MDH receives a CD4+ count on a patient, they look at whether that person is already known to MDH, the doctor ordering the test, and if the person is at an advanced age. If the person is not already known to MDH as an HIV-positive case or the doctor ordering the test is not an infectious disease doctor, or the person is of advanced age, all the information, including test results and any demographic information, is discarded and shredded, nothing is kept on file. MDH only reviews the CD4 count tests from infectious disease doctors because these are the doctors that work with HIV patients.

In summary, the proposed change will clarify the laboratories' reporting requirements for HIV/AIDS cases. The amendment will make explicit that laboratories must report all CD4+ lymphocyte counts and percents and all HIV viral detection, detected and undetected, test results to MDH. This amendment is necessary and reasonable to ensure that persons currently living and receiving HIV/AIDS care in the State are reported. In addition, it will allow MDH to accurately depict Minnesota's HIV epidemic, which, in turn, will allow for more accurate planning for both prevention and care. Moreover, MDH needs these changes to stay current with medical advances to carry out its public-health mandate for responding the HIV/AIDS epidemic.

Moreover, on November 16, 2010, the Centers for Disease Control and Prevention (CDC), sent a letter to all state health departments recommending "that all states and territories

work towards ensuring supportive state policy for reporting all HIV-related CD4+ T-lymphocyte (CD4) results and all viral loads” in order to achieve the nationwide goal of comprehensive laboratory reporting for HIV surveillance. The letter goes on to say that these tests are an “essential component of national HIV surveillance system” that can be “used to identify cases, classify states of disease at diagnosis, and monitor disease progression.” “These data can also be used to evaluate HIV testing and prevention efforts ... and assess unmet healthcare needs.” (Attachment C). Minnesota will also be able to measure its progress in achieving the national HIV/AIDS strategy goals. These goals can be found at <http://www.whitehouse.gov/administration/eop/onap/nhas/>

Finally, by enacting these changes, Minnesota will join the majority (85 percent) of the federally funded jurisdictions for HIV Surveillance that require laboratories to specifically report all viral detection test results, detected and undetected, as well as, all CD4+ counts and percents.

There were a few concerns about privacy, which are discussed below. One person asked whether negative test results would be reported. MDH responded that negative test results do not need to be reported. It is possible that an HIV-positive patient will have no discernable amount of virus under the HIV viral detection test. This is not considered to be a “negative” test, but merely “undetectable.” The individual is still HIV-positive and the test results will provide MDH with information on the progress of the disease and the fact that the person is receiving care for their HIV infection.

Second, MDH already collects information on HIV-positive individuals. This information is crucial to ensure the well being of all Minnesotans and to help prevent the spread of HIV/AIDS and provide those infected with appropriate treatment.

Finally, based on experience from laboratories that currently report CD4+, it is known that 99 percent of the CD4 counts that MDH receives will be related to HIV cases. However, there may be a very small percentage reported that are related to cancer patients. MDH will cross reference the name with MDH registry of HIV patients and also look to see what type of doctor requested the test. If the person is not on our registry and the requesting provider is not an infectious-disease doctor, the information will be disposed of by shredding and MDH will not keep any information on that person.

The second amendment in 4605.7030, subpart 4 excludes institutions that include laboratories from being able to assign one person to submit all reports of CD4+ lymphocyte counts and percents and HIV detection tests. This is a technical amendment and is necessary to ensure this part is consistent with the intent of the first proposed amendment in subpart 3, which is to make sure that laboratories report all HIV detections tests and CD4+ lymphocyte counts and percents.

Both these amendments are reasonable and necessary to ensure accurate diagnostic testing for HIV/AIDS so that the state can institute proper disease control measures and get an accurate count of people living with HIV in Minnesota for prevention and care planning.

VII. LIST OF EXHIBITS

In support of the need for and reasonableness of the proposed rules, MDH anticipates that, if a hearing is held, it will enter as exhibits the following: (Attachment C), Statements of Support from the following organizations:

- Center for Disease Control and Prevention, HIV Incidence and Case Surveillance Branch
- Quest Diagnostic Laboratory
- Hennepin County Department of Public Health, Ryan White Program
- Minnesota Department of Human Services, HIV Program

VIII. CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

February 2010

Edward P. Ehlinger, MD, MSPH, Commissioner
Minnesota Department of Health

LIST OF ATTACHMENTS

Attachment A	Glossary of Terms
Attachment B	Methods of Notifying and Persons Notified of Request for Comments
Attachment C	CDC Recommendation for Reporting of CD4+ T-lymphocyte (CD4 results and viral load
Attachment D	Letters of Support

ATTACHMENT A

Glossary Of Terms

AIDS. (Acquired Immune Deficiency Syndrome.) It is a disease caused by the HIV virus.

antibody. A protein produced in the blood by the immune system that helps identify and destroy foreign germs (e.g., viruses or bacteria) that attack the body. Antibodies can be produced in response to a vaccine or to a natural infection. They circulate in the blood to protect against future infections.

antigen. A protein on the surface of a virus, bacteria or cell that can stimulate the immune system to produce antibodies as a defense mechanism.

assay. A type of diagnostic test.

CD4+ count test. This test measures the amount of CD4 cells (a lymphocyte) also known as T-cells, or “helper cells” in a person’s body. This can be measured as an absolute number or as a ratio (percent) in relation to the total number of lymphocyte cells in the body. The result of this test provides a measure of the strength of a person’s immune system.

CDC. The abbreviation for the Centers for Disease Control and Prevention. A federal agency under the U.S. Department of Health and Human Services that serves as “the nation’s health department.”

CSTE: Council of State and Territorial Epidemiologists, a national organization that recommends policies for epidemiologists working at the state level.

epidemiology. The study of the distribution and determinants of disease, injury, and other health-related events.

HIV. (Human Immunodeficiency Virus) It is a retrovirus that causes immune system failure and debilitation. It is the virus that causes AIDS.

incidence of disease. The number of new cases of a specific disease occurring during a certain period of time in the population.

infectious agent. An organism that is capable of producing an infection or an infectious disease.

prevalence. The number of cases of a disease that are present in a population at a specified time, either at a point in time or over a period of time.

rapid test. A blood test that detects antibodies to HIV in screened persons.

sensitivity. Sensitivity of a test refers to the proportion of positive test results that are correctly identified as such. For example, the current HIV rapid test has close to 100% sensitivity, meaning that a positive result is very likely to indicate that the individual is positive.

specificity. Specificity of a test refers to the proportion of negative results that are correctly identified as such. A test with high specificity means that very few people who have an infection will be identified as negative by that test.

undetectable viral load. This means that the test is not sensitive enough to detect the virus in the person, but the person is still HIV positive. When people with HIV have an undetectable viral load, it means they are less likely to become sick, and it is less likely that their anti-HIV medications will stop working.

viral detection test. Looks for HIV-1 DNA in the in the white blood cells of a person, whereas the HIV antibody ELISA and HIV antibody Western blot assays measure the immune response to the virus, e.g., HIV-1 PCR test

western blot test. A laboratory test used to detect specific proteins in a tissue sample, such as blood. This test looks for HIV antibodies and can confirm if a person is infected with the HIV v

Attachment B

Methods of Notifying and Persons Notified of Request for Comments

1. Mailed the Request for Comments to all persons who had registered to be on MDH's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.
2. Posted the Request for Comments and a copy of the draft rules on MDH's communicable disease rule web site at www.health.state.mn.us/divs/idepc/diseases/hiv/hivreportingrule.html and at the MDH HIV web site at www.health.state.mn.us/HIV.
3. Provided a summary of the Request for Comments and a web link to the proposed rules via e-mail, directly or through a listserve, to various individuals, groups, and organizations in Minnesota. MDH also requested that these organizations post the information on their website and forward the information to other interested parties. The list included, but was not limited to:
 - MDH's infection control practitioner list
 - Medical laboratories on MDH's Minnesota Laboratory System list. This list includes approximately 160 laboratories, including public health and private clinical laboratories, as well as veterinary and agriculture laboratories, which serve Minnesota residents.
 - Minnesota Medical Association
 - Minnesota AIDS Project (MAP)
 - Hennepin County Ryan White Program
 - Minnesota Department of Human Services (DHS)
 - State HIV Grantees



ATTACHMENT C

**CDC Recommendation for Reporting of
CD4+ T-lymphocyte (CD4 results and viral load**



November 16, 2010

Dear Colleague:

Measuring progress towards several goals of the National HIV/AIDS Strategy relies on laboratory reporting of HIV-related tests to the local and national HIV surveillance systems. In order to achieve the nationwide goal of comprehensive laboratory reporting for HIV surveillance, the Centers for Disease Control and Prevention (CDC) recommends that all states and territories work towards ensuring supportive state policy for reporting all HIV-related CD4+ T-lymphocyte (CD4) results and all viral load test results. Comprehensive laboratory reporting is in alignment with the Council of State and Territorial Epidemiologists' (CSTE) position (ID: 2001-ID-03 Committee: Infectious Disease Title: The impact of new technologies and therapies on HIV/AIDS surveillance: routine nationwide reporting of CD4, STAHRS, antiretroviral resistance, and viral load test results).

Laboratory data, including CD4 and viral load test results, are an essential component of the national HIV surveillance system. CD4 and viral load data can be used to identify cases, classify stage of disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into care and retention in care, measure viral load suppression, and assess unmet healthcare needs. Analyses at the national level can only occur with the adoption and implementation of the reporting of all HIV-related CD4 and viral load test results by all jurisdictions.

The implementation of state policies supporting the reporting of CD4 and viral load test results by laboratories has led to increased reporting and enhanced the completeness and timeliness of HIV surveillance data. Although the majority of jurisdictions have policies, laws, or regulations that require laboratories to report CD4 and viral load results, the level at which these laboratory results are reported to HIV surveillance programs varies within and across states. To this end, CDC recommends that all HIV surveillance programs work towards supportive state policies for reporting of all HIV-related CD4 results (counts and percentages) and all viral load results (undetectable and specific values).

CDC is committed to providing the technical assistance necessary to make enhanced laboratory reporting occur with minimal disruption to ongoing HIV surveillance. For further information, or to request technical assistance, you may contact Dr. Irene Hall, HIV Incidence and Case Surveillance Branch, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, telephone (404) 639-2050, e-mail (IHallI@cdc.gov).

Page 2 – Dear Colleague

As always, thank you for your continued, dedicated efforts to prevent HIV infection in the United States and around the world.

Sincerely,

/Jonathan H. Mermin/

Jonathan H. Mermin, M.D., M.P.H.
Director,
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral
Hepatitis, STD, and TB Prevention

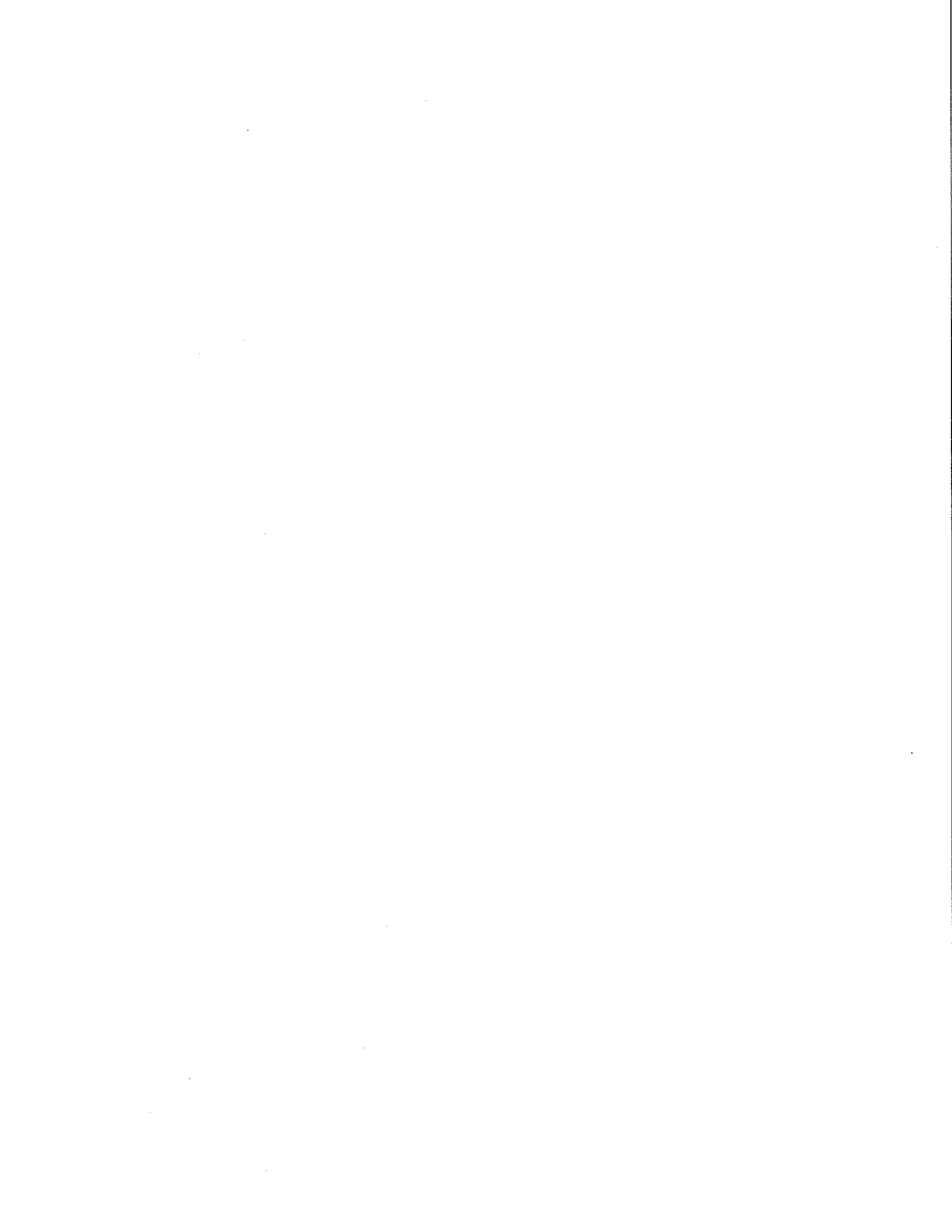
References

Link to National HIV/AIDS Strategy:

<http://www.whitehouse.gov/administration/eop/onap/nhas>

Link to CSTE position statement:

[http://www.cste.org/ps/pssearch/2001final/2001-ID-03.pdf#search="hiv](http://www.cste.org/ps/pssearch/2001final/2001-ID-03.pdf#search=)



Letters of Support

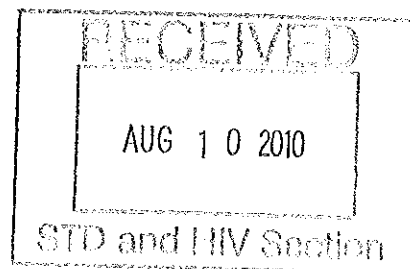
1. H Irene Hall, Branch Chief, HIV Incidence and Case Surveillance
Branch, Centers For Disease Control and Prevention
2. Todd Monson, Area Director Hennepin County Human Services Public
Health Department
3. Dave Rompa, Program Administrator, HIV AIDS Unit, Minnesota
Department of Human Services



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

August 4, 2010

Luisa Pessoa-Brandão, MS
Epidemiology and Surveillance Unit Supervisor
HIV/AIDS Surveillance Coordinator
STD & HIV Section
Minnesota Department of Health
625 Robert Street N.
St. Paul, MN 55155-2538



Dear Ms. Pessoa-Brandão:

We are sending this letter in an effort to support the transition to laboratory reporting of all HIV-related CD4+ T-lymphocyte (CD4) and viral load test results from private and public laboratories to the Minnesota Department of Health.

In order to achieve the nationwide goal of comprehensive laboratory reporting to HIV surveillance, the Centers for Disease Control and Prevention (CDC) *recommends* that states and territories adopt mandatory reporting of *all* HIV-related CD4 and viral load test results. Complete CD4 and viral load reporting enhances local and national surveillance data and can be used to stage disease at diagnosis, monitor disease progression, evaluate HIV testing and prevention efforts, determine entry and retention in care, measure viral load suppression, and assess unmet healthcare needs.

The implementation of state policies that support the reporting of CD4 and viral load test results by laboratories has led to increased reporting and has enhanced the completeness and timeliness of HIV surveillance data. Although the majority of jurisdictions have policies, laws, or regulations that require laboratories to report CD4 and viral load results, the level at which these laboratory results are reported to HIV surveillance programs varies within and across states. To this end, CDC *recommends* that HIV surveillance programs work towards ensuring state policy is supportive of the reporting of all HIV-related CD4 results (counts and percentages) and all viral load results (detectable and undetectable).

Sincerely,

H Irene Hall, PhD, FACE
Branch Chief
HIV Incidence and Case Surveillance Branch
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
1600 Clifton Road, NW, MS E-47
Atlanta, GA 30333



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612-348-0022 TTY
www.hennepin.us

July 21, 2010

Peter Carr
Minnesota State AIDS Director
Minnesota Department of Health, HIV/STD Section
PO Box 64975
St. Paul, MN 55164-0975

Dear Peter:

I am writing to express Hennepin County Human Services and Public Health Department's support of the amendment to Minnesota's communicable disease reporting rules that will require all laboratories to report to the Minnesota Department of Health the results of all CD4+ lymphocyte counts and percents and the results of all HIV viral detection tests.

As the Ryan White Part A grantee for the Minneapolis-St. Paul Transitional Grant Area (TGA), Hennepin County relies on the most accurate surveillance of HIV/AIDS incidence and prevalence to effectively plan for the use of Ryan White grant funds to ensure access to medical care and antiretroviral treatment. An accurate estimate of unmet need for medical care, the proportion of Minnesotans living with HIV who know their status and have not accessed medical care, is a key component of Hennepin County's annual competitive application for supplemental Ryan White Part A funding for HIV services in the TGA. A person living with HIV/AIDS who has unmet need is defined by the Health Services Resource Administration as someone who has not had a CD4 count or viral load test in the past twelve months. The estimate of unmet need is used to help make a case for severe need for resources to assure access to care for low-income people living with HIV/AIDS. How well Hennepin County presents the case for severe need in the annual Ryan White Part A grant application determines the amount of funds awarded.

Currently the laboratories used by two of the largest HIV specialty clinics in the Twin Cities metropolitan area do not routinely report CD4 counts and viral load tests, limiting the accuracy of the unmet need estimate. Requiring all laboratories to do so will improve the estimate of unmet need and strengthen Hennepin County's application for Ryan White Part A funding. In addition, a more accurate unmet need estimate will improve the information the Minnesota HIV Services Planning Council uses to prioritize services and allocate Ryan White Part A and B funds to ensure that all low-income people living with HIV/AIDS in Minnesota access primary medical care and antiretroviral therapy early. Complete reporting of CD4 counts and viral load tests will also help identify race, ethnic, gender and mode of HIV exposure disparities in early access to treatment.

I appreciate the opportunity to voice support for the amendment to change the communicable disease reporting rules for HIV infection. We look forward to a more accurate estimate of unmet need for HIV medical care resulting from a more complete reporting of CD4 counts and viral load tests in the future.

Sincerely,

A handwritten signature in black ink that reads 'Todd Monson'.

Todd Monson
Area Director

From: Rompa, Dave (DHS)
Sent: Thursday, July 22, 2010 2:09 PM
To: *MDH_HIVLabRule
Subject: Department of Human Services HIV/AIDS Unit

The HIV/AIDS Unit of the Disability Services Division of the Department of Human Services supports the rule change that all laboratories must report to the Minnesota Department of Health the results of all CD4+ lymphocyte counts and percents and the results of all HIV detection laboratory tests. Accurate epidemiological data is essential to public health concern, federal reporting, disease maintenance planning and in securing funding for program services.

Dave Rompa
Program Administrator
HIV/AIDS Unit
Disability Services
Department of Human Services



ATTACHMENT C

**CDC Recommendation for Reporting of
CD4+ T-lymphocyte (CD4 results and viral load**



November 16, 2010

Dear Colleague:

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CDC is committed to providing the technical assistance necessary to make enhanced laboratory reporting occur with minimal disruption to ongoing HIV surveillance. For further information, or to request technical assistance, you may contact Dr. Irene Hall, HIV Incidence and Case Surveillance Branch, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, telephone (404) 639-2050, e-mail (IHallI@cdc.gov).

Page 2 – Dear Colleague

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/Jonathan H. Mermin/

Jonathan H. Mermin, M.D., M.P.H.
Director,
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References

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Letters of Support

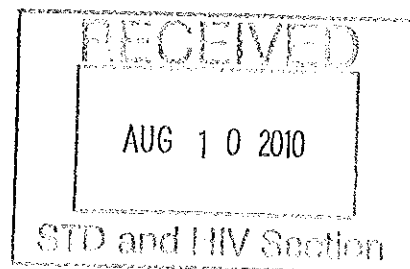
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Dave Rompa
Program Administrator
HIV/AIDS Unit
Disability Services
Department of Human Services