Significant Analysis
HIV Testing, Counseling and Partner Services (formerly partner notification)
Sections, -072, -207, -208 and -209 of Chapter 246-100
Washington Administrative Code (WAC)

Briefly describe the proposed rule - background

Human immunodeficiency virus (HIV) counseling and testing and HIV partner services (formerly known as partner notification) rules were substantially revised in 2005 to remove many access barriers to HIV testing and local health jurisdiction involvement in HIV partner services. In September 2006, the Centers for Disease Control and Prevention (CDC) issued Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Healthcare Settings.

The Department of Health (Department) received a number of comments from medical facilities, health care providers, and local health jurisdictions stating confusion about current State Board of Health (Board) rule language that was not aligned with CDC recommendations. Providers of HIV testing, counseling and partner services were uncertain whether the state rule or federal recommendations took precedent in current practice.

Between October and December 2006, the Governor's Advisory Council on HIV/AIDS and the regional AIDSNETs (six AIDS service networks in Washington) requested the Department to identify inconsistencies between state rules and CDC recommendations. Department staff recommended to the Board that the community have an opportunity to adjust to the 2005 rule changes prior to considering work on additional revisions.

In 2008, the AIDSNET Council sought support from state and local medical associations on their issue papers recommending rule changes to align HIV testing and partner services language with current CDC recommendations. These issue papers were endorsed by the Washington State Association of Local Public Health Officials, local health officers and the Washington State Medical Association. Letters of support for the issue papers were submitted to the Department and the Board.

Department staff worked closely with major stakeholders to ensure their participation and input in drafting proposed language that would update the current standards to support the goals and objectives of the authorizing statute, which is to control and treat sexually transmitted disease (STDs). In doing so, the proposed language will align the current rule language with the CDC's 2006 recommendations for HIV testing and 2008 recommendations for partner services.

Section 1. What is the scope of the rule?

The proposed rule will make state rules for HIV counseling and testing and partner services more consistent with the CDC's most current recommendations:

- "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings," September 2006;
  - HIV screening is recommended for patients age 13 to 64 in all healthcare settings and as a part of a routine panel of prenatal screening for all pregnant women
  - HIV screening is recommended after a patient or pregnant woman is notified that testing will be performed unless the patient declines – opt-out consent
  - No longer require separate written consent from patient or pregnant woman for HIV testing; general consent for medical care should be sufficient to include HIV testing
  - Counseling is no longer recommended with HIV testing in a healthcare setting.
- "Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection," October 2008;
  - Strongly recommends that all persons with newly diagnosed or reported HIV infection or early syphilis receive partner services with active health department involvement.

The proposed changes will reduce barriers for providers offering routine screening for HIV and makes the testing process easier so providers are more likely to offer HIV testing to a larger segment of the population. The intent is to reduce the stigma associated with HIV testing by making it a part of routine medical exams. These changes may inform more individuals of their HIV status and the benefit of treatment and potentially reduce HIV transmission including perinatal HIV transmission.

Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?

The general goal of chapter 70.24 of the Revised Code of Washington is to control and treat sexually transmitted disease (STDs).

The objectives of this rule chapter are to:
1) Provide STD programs sufficient flexibility to meet emerging needs, and
2) Efficiently and effectively reduce the incidence of STDs.

Section 3. What is the justification for the proposed rule package?

Objective 1: Provide STD programs sufficient flexibility to meet emerging needs.
1) The proposed rule change eliminates the requirement for health care providers to obtain explicit verbal or written informed consent prior to administering an HIV test. Eliminating this requirement will allow health care providers the flexibility to offer HIV screening to all Washington residents ages 13 to 64, which will increase the number of people being tested. Proposed rule language does require the health care provider to specifically inform the individual verbally or in writing when an HIV test is being performed. HIV community stakeholders expressed strong support of this proposed

provision in the rule language during public meetings to ensure that individuals were aware that HIV testing would be performed.

2) The proposed rule change eliminates the requirement to provide pre-test counseling prior to prescribing an HIV test. This revision aligns rule language with the CDC 2006 HIV testing recommendations that no longer recommends HIV counseling with HIV testing.

3) The proposed rule change grants local public health providers permission to directly contact a patient to provide partner services as recommended by the CDC 2008 recommendations.

Objective 2: Deal efficiently and effectively with reducing the incidence of STDs.
The CDC recommends HIV screening for all persons ages 13 to 64 in all health care settings to effectively reduce the annual incidence of HIV infections. The CDC further recommends that HIV screening is most efficiently accomplished if informed consent for HIV testing is part of a general consent for care and that pre-test counseling is not required. Studies have shown that patients who aware they are HIV-positive generally change their sexual and drug using behavior so they do not transmit the virus to their partners. This awareness will result in reducing the incidence of STDs.[1] These recommendations are incorporated into the proposed rule.

Lastly, this rule change is necessary to implement the new *CDC Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings* in Washington including the provision to make screening routine for all residents 13 to 64. Stakeholders, including public health and other health care providers, perceive the current provisions in rule for HIV testing, counseling, and partner services as exceptional to common practice and create barriers to providing these services.

Section 4. What are the probable costs and benefits of each rule included in the rule package? What is the total probable cost and total probable benefit of the rule package?

There are four sections in this rule package within chapter 246-100 WAC - *Communicable and certain other diseases*:

- 246-100-072 - *Rules for notification of partners at risk of HIV infection*

[1] CDC Morbidity and Mortality Weekly Report (MMWR), Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings; September 22, 2006 / 55(RR14);1-17 CDC MMWR, Advancing HIV Prevention: New Strategies for a Changing Epidemic --- United States, 2003; April 18, 2003 / 52(15);329-332

- 246-100-207 - *Human immunodeficiency virus (HIV) testing -- Ordering -- Laboratory screening -- Interpretation – Reporting*

- 246-100-208 - *Counseling standard -- AIDS counseling*

- 246-100-209 -*Counseling standards – Human immunodeficiency virus (HIV) pre-test counseling – HIV post-test counseling*

The proposed rule requires a significant analysis because it will make significant changes to an existing program policy. However, the Department determined that no significant analysis is required for the following section of the rule because the analysis of the proposed changes will be done in other parts of the section-by-section analysis.

Non-Significant Rule

#	WAC Section	Chapter Title	Section Subject	Reason
1	WAC-246-100-209	Communicable and certain other diseases	Counseling standards – Human immunodeficiency virus (HIV) pretest counseling – HIV post-test counseling	Removes requirements for health care providers to provide post test counseling. Makes language consistent with proposed changes in section 072 of this WAC.

The following three sections are considered significant and analyzed below. The proposed rule revision does not mandate any party to provide or to participate in any HIV testing activities. It simply allows providers to more readily offer the option of HIV testing to their clients. Therefore, no cost is associated with this rule revision.

WAC 246-100-207 ***HIV testing-Ordering-Laboratory screening-Interpretation-Reporting***

Rule Overview – The proposed revision amends this section to require any person ordering or prescribing an HIV test for another individual to obtain the informed consent of the individual, separately or as part of the consent for a battery of other routine tests, provided the individual is specifically informed in writing or verbally that a test for HIV is included. It also requires that the individual is offered an opportunity to ask questions and decline testing. If the HIV test is positive or suggestive of HIV infection, the person ordering or prescribing the test must provide the name and locating information of the individual to the local health officer for follow-up to provide post-test counseling.

This section is also amended to require the local and state health officer to periodically make efforts to inform providers in their jurisdiction about the CDC recommendations for HIV testing, and states that healthcare providers may obtain a brochure about the CDC recommendations by contacting the Department. Public health officials have mechanisms in place to communicate with health care providers in their communities (newsletters, medical society meetings), therefore, no cost is associated with this proposed language change.

Benefits/Rationale for proposed changes to WAC 246-100-207 – The current rule language does not align with CDC recommendations. The current language requires a person to; 1) evaluate individual for clinical or behavioral risk factors, 2) get explicit verbal or written informed consent from an individual prior to ordering or prescribing an HIV test, 3) recommend, offer or refer for HIV pretest counseling, 4) provide or ensure completion of post-test counseling. The contradicting language between rule and CDC recommendations confuses healthcare providers and prevents them from implementing CDC recommendations for routine screening of all persons ages 13 to 64 in all health care settings. In some cases, this contradiction may keep providers from offering testing. The CDC recommends that consent for HIV testing be included in a general consent for medical care and that pre-test counseling should not be required as part of HIV screening in health care settings. The Department estimates approximately 10 to 20 percent of Washington residents infected with HIV are unaware of their infection. Revising the rule will likely result in a proportion of these individuals knowing their HIV status, enabling them to take advantage of life saving medical treatments, and reduce the number of new HIV infections.

WAC 246-100-208 ***Counseling standards-AIDS counseling***

Rule Overview – The proposed language amends this section regarding AIDS counseling standards for pregnant women and requires the health care provider to obtain the informed consent of the pregnant woman, separately or as part of the consent for a battery of other routine tests, provided the woman is specifically informed in writing or verbally that a test for HIV is included. It also requires that the woman is offered an opportunity to ask questions and decline testing. If the woman refuses testing, the health care provider is required to discuss and address the reasons for her refusal and to document the refusal and the provision of education on the benefits of testing in the medical record. If the HIV test is done and is positive or suggestive for HIV infection, the health care provider must provide the name and locating information of the woman to the local health officer for follow-up and reporting as required by WAC 246-100-209.

Benefits/ Rationale for proposed changes to WAC 246-100-208 - HIV-positive pregnant women that receive treatment are less likely to transmit HIV to their newborn.

The proposed rule language eliminates the requirement for the principal health care providers to perform an HIV risk assessment and behavioral change counseling. The

CDC recommends HIV screening for all pregnant women after the patient is notified that testing will be performed, unless the patient declines, and that AIDS counseling should not be required as part of HIV screening programs in health-care settings.

WAC 246-100-072 ***Rules for notification of partners at risk of HIV infection***

Rule Overview – The proposed revision requires the local health officer to attempt to contact the principal health care provider within three days of receiving a report of a case of HIV. This change makes the rule consistent with performance measures established in response to Engrossed Second Substitute Bill 5930. The bill passed during 2007 state legislative session and required the Department to develop performance measures linked to new funding for public health at the local level. The local health officer is required to contact the principal health care provider of a newly diagnosed HIV infected person to seek input on the best means of conducting a case investigation including partner services. It eliminates the health care provider's option to recommend that the health officer *not meet* with the HIV infected person for the purposes of partner services, and the health care provider's option to provide partner services assistance to the HIV infected person themselves.

Previous CDC guidelines for HIV partner counseling and referral services have recommended interactive, client-centered prevention counseling for partners, and referral of individuals to medical care. CDC's 2008 partner services guidelines continue those recommendations. The proposed revisions explicitly identify that post-test counseling is an integral part of partner services.

The proposed revision adds new requirements for the health officer to contact the health care provider to remind the provider of the health officer's responsibility to conduct partner services. The revision also requires the health care provider to inform the HIV infected person that the local health officer or authorized representative will contact the HIV infected person to assist them with notification of partners.

Benefits/ Rationale for proposed changes to WAC 246-100-072 – This rule revision poses no new costs to local health because the rule affects work that local health jurisdictions already perform. The rule will likely result in local health jurisdictions providing partner services to the estimated 10 to 20 percent of HIV infected individuals who are not yet aware of status as health care providers more routinely test for HIV.

The current WAC 246-100-072 requires the health officer to get *agreement* from the health care provider before contacting the HIV infected person for purposes of providing assistance with partner services, and it permits the principal health care provider to recommend that the health officer *not meet* with the HIV infected person for purposes of notifying partners. These requirements do not apply to other sexually transmitted diseases and conflict with CDC 2008 recommendations that local health officials should be directly involved in partner services activities for all reported HIV cases.

Few health care providers have any training in partner services assistance whereas this is a primary area of responsibility and expertise for local health departments. The exceptional requirements in current rule language act as barriers to healthcare providers routinely offering partner services assistance to HIV infected individuals. It is likely that individuals with exposure to HIV are not being made aware of their exposure to HIV and are not being provided an opportunity to test for HIV infection and reduce their risk of future exposure. The proposed revisions still require the local health officer to contact the principal health care provider to determine the best means of partner services.

Evidence shows that more partners are notified when the local health department is involved in partner services as compared to when partners are notified by the patient (patient directed partner services).[2] Revising the rule will likely result in a proportion of these individuals knowing their HIV status, enabling them to take advantage of life saving medical treatments, and reduce the number of new HIV infections.

Rule Cost-Benefit Conclusion

The benefits of the proposed rule include:

The CDC, the Institute of Medicine, the American Medical Association, and many other national health organizations support efforts to increase the number of people who learn their HIV status. The proposed rule revision will decrease barriers that currently exist for many people to get HIV testing and to learn their HIV status.

The Department estimates 10 to 20 percent of people infected with HIV in Washington are not aware of it and do not seek medical care that can help keep them healthy and extend their lives. In addition, they do not have the knowledge to protect their sex or drug-using partners from becoming infected, and as a result, cannot take steps to help reduce the spread of the virus. This proposed rule revision will benefit state residents in the following ways:

- Reduce barriers to HIV testing (which will increase the number of residents that are aware of their HIV status),
- Enhance the health of individuals who are HIV infected (by receiving treatment earlier), and
- Reduce the number of new HIV infections (patient awareness is key in preventing transmission of HIV).

The proposed rule revision does not mandate any party to provide or to participate in any HIV testing activities. It simply allows providers to more readily offer the option of HIV testing to their clients.

Results from a cost-effective analysis by Varghese, Peterman and Holtgrave revealed that "for a cohort of 10,000 individuals at a clinic with an HIV seroprevalence of 1.5%, we

[2] CDC MMWR, Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydia Infection; October 30, 2008 / 57(Early Release);1-63

estimate that counseling and testing prevents eight HIV infections and saves society almost $1,000,000. We estimate that partner services for the 113 infected persons identified by counseling and testing prevents another 1.2 HIV infections and saves an additional $181,000. To the provider (HIV and STD clinics), this translates to a cost of $32,000 per case prevented by counseling and testing and an additional $28,000 for partner services. Model results are most sensitive to assumptions of HIV prevalence, risk of transmission, and treatment cost of HIV."[3]

Results from a cost-effective analysis by Sanders, et. al, conclude that "the cost-effectiveness of routine HIV screening in health care settings, even in relatively low-prevalence populations, is similar to that of commonly accepted interventions, and such programs should be expanded."[4]

As the preceding sectional analysis demonstrates the department assumes there are no compliance costs associated with this rule revision, there are only benefits. Therefore, the probable benefits exceed the costs.

Section 5. What alternative versions of the rule did you consider? Is the proposed rule the least burdensome approach?

Department staff worked with stakeholders and the public in collaborative rulemaking to minimize the burden of this rule. Many meetings were held with interested parties on the East (Spokane) and West (Seattle and Tumwater) sides of the state to inform the public and stakeholders of this rule revision and draft language. All meeting documents and draft language are posted on the Department's HIV Prevention and Education Services Section web page. The AIDSNET Council, Statewide HIV/AIDS Planning Group, Governor's Advisory Council on HIV/AIDS, and Lifelong AIDS Alliance were briefed as key constituent groups on the intent and progress of this rule revision.

Alternative #1: Do nothing – maintain current rule language
The CDC recommendations cannot be implemented without this rule revision. The AIDSNET and Washington State Medical Association initiated the request to amend rule language because it doesn't align with current CDC recommendations for HIV testing, counseling, and partner services. The Board has determined that the CDC recommendations are important to control and treat STDs. If the Board chooses to "do nothing", the current rule language remains confusing and prevents more individuals from knowing their HIV status, getting appropriate services and treatment if HIV-positive, and decreasing the number of new infections.

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[3] Cost-effectiveness of counseling and testing and partner notification: a decision analysis; Journal of AIDS; September 10, 1999

[4] Cost Effectiveness of Screening for HIV in the Era of Highly Active Antiretrovial Therapy; New England Journal of Medicine; February, 10, 2005

Section 6. Did we determine that the rule does not require anyone to take an action that violates another federal or state law?

This rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law?

The rule does not impose more stringent performance requirements on private entities than on public entities.

Section 8. Did we determine that the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?

This rule does not differ from any federal regulation or statute applicable to the same activity or subject matter.

Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter?

This rule is coordinated, to the maximum extent practicable with other applicable laws. The goal of this revision is to align rule language with the latest CDC recommendations.