November 16, 2007

Frequently Asked Questions about Changes in Licensed Laboratory HIV Test Reporting in Oregon

HIV/STD/TB Section, Oregon State Public Health Division
971-673-0153

Is it true that licensed laboratories are no longer required to collect a "consent" form before testing specimens for HIV?

Yes, this is true as of January 16, 2007. For years, Oregon Administrative Rule (OAR) 333-018-0030 required laboratories to collect an HIV Report Form (OHD 49-03) on which the doctor or other clinician signed an attestation to the fact that the patient had provided informed consent for testing. OAR 333-018-0030 no longer mandates collection of the form.

Where does it say in Oregon Rule or Statute that the testing ("consent") form is no longer required?

Nowhere in current rule or statute does it explicitly say that the testing form is no longer required. The change is effected by the absence of language requiring the testing form. Prior to January 16, 2007, collection and submission of the HIV Report Form was required under Oregon Administrative Rule 333-018-0030. This language was stricken from the rule effective upon its filing with the Secretary of State on January 16, 2007. A copy of the new rule is posted on the HIV/STD/TB Section (HST) website (http://oregon.gov/DHS/ph/hst/index.shtml).

What must licensed laboratories in Oregon report quarterly about HIV testing beginning in 2007?

As a result of the revision of Oregon Administrative Rule 333-018-0030, laboratories will be henceforth required to provide quarterly reports to Oregon State Public Health Division, HIV/STD/TB Section beginning with the first quarter of 2007. As outlined in the text of the rule, these reports must be comprised of a summary of the number of individuals tested and the number with HIV-positive test results grouped by sex, age category (<5 years, 5–12 years, 13–19 years, 20–29 years, 30–39 years, 40-49 years, 50–64 years, and ≥65 years), and type of test used. The reports shall be submitted via electronic means in comma separated or other format mutually agreeable to DHS and reporting laboratory. These summary reports should not otherwise identify individuals. Laboratories may contact the Data and Analysis Program (971-673-0181) of the HST Section to arrange to submit quarterly reports. Laboratories that do not perform HIV diagnostic tests on sight, but send specimens to a reference laboratory need not submit quarterly reports of HIV testing.

Why must laboratories submit quarterly reports about HIV testing beginning in 2007?

The Oregon State Public Health Division and the HST Section have traditionally used the HIV Test Report Forms to track the quantity of HIV testing statewide in Oregon. With the abandonment of the individual testing form, HST needed an alternative method of quantifying HIV testing in Oregon. In discussion with an advisory committee from the medical community and public health colleagues, public health officials determined that quarterly summary reports would be the least onerous way to collect this information.

In which format should we create HIV testing reports?

The HST Section would prefer to receive quarterly reports electronically in ASCII, Microsoft Excel®, comma separated or other common electronic format. Reports should tabulate the number of HIV diagnostic tests performed—positive, negative or indeterminate—during the most recent calendar quarter. Tests should be summarized by type of test (e.g. HIV antibody test—rapid or traditional EIA, qualitative or quantitative RNA if done for diagnosis, other tests for HIV diagnosis [If not otherwise known to have been requested for diagnosis, quantitative viral loads and other non-antibody tests can be assumed to have been done for clinical monitoring and should be omitted from quarterly report.]), sex, result (positive, negative, indeterminate). A sample report is shown below.

Since the reports should not contain individual identifying information they can be emailed to HST section (sean.schafer@state.or.us). Reports can also be submitted by fax (*971-673-0179)* or mail to: HIV Testing Quarterly Laboratory Reporting; HIV/STD/TB Section, 800 NE Oregon St., Suite 1105, Suite 1105; Portland, OR 97232; Attn: Lea Bush or Denise Skrypkar. Contact the HIV Data and Analysis Program at 971-673-0153 for alternative transmission methods.

Reporting Laboratory: XYZ Clinical Laboratory Reporting Period: Q1, 2007 (Jan 1 – March 31)																		
Test Type (e.g., HIV antibody test—rapid or traditional EIA, qualitative or quantitative RNA if done for diagnosis, other tests for HIV diagnosis)		Test Type #1						Test Type #2						Test Type #3					
Sex		Male			Female			Male			Female			Male			Female		
Result		Neg	Pos	Ind	Neg	Pos	Ind	Neg	Pos	Ind	Neg	Pos	Ind	Neg	Pos	Ind	Neg	Pos	Ind
Age Group (Years)	<5																		
	6–12																		
	13–19																		
	20–29																		
	30–39																		
	40–49																		
	50–64																		
	≥65																		

How should we create testing reports if sex or age group of the patient is unknown for some or all of our HIV test reports?

The HIV/STD/TB Section recommends that your laboratory create unknown categories for age and sex to handle these instances.

If our laboratory refers all HIV testing to an independent reference laboratory, are we required to submit quarterly testing reports?

In many if not all cases, the reference laboratory will do the quarterly reporting on behalf of the referring laboratory. Referring laboratories should check with their reference laboratory(s) to confirm that they will submit quarterly reports that include testing done on behalf of the referring lab. If the reference laboratory is not planning to submit reports on behalf of the referring laboratory, the referring laboratory should make plans to submit quarterly summary reports of HIV testing.

Our laboratory does HIV testing for many different hospitals and health care facilities. Is it necessary to break out the quarterly reports by facility where the sample was collected?

The reporting is intended to be by laboratory, not ordering facility, so labs are not required to report testing by ordering facility. If a laboratory finds it more convenient to group the quarterly reports by ordering facility, this will be acceptable.

Our laboratory already reports HIV-related tests via electronic laboratory reporting (ELR). Is it necessary for us to create these aggregate quarterly reports in addition to ongoing ELR?

If laboratories that already report via ELR wish to include individual HIV diagnostic testing results (including both positive and negative tests) with their other ELR data, they do not need to submit a quarterly summary report. In contrast to viral loads, CD4 counts, and positive diagnostic test data, negative HIV diagnostic test data should not include name or other identifiers except sex and age or age group. Laboratories that wish to expand ELR to meet this requirement can make these arrangemets with JA Magnuson at 971-673-1030.

Until such time as ordering providers become aware that the testing forms are no longer required, what should our laboratory do with testing forms that continue to arrive with specimens for HIV testing?

Neither the Oregon State Public Health Laboratory nor the HIV/STD/TB Section wishes to continue to receive testing forms from private laboratories after January 16, 2007. Any testing forms that you receive after this date should not be sent to the state. You may handle these forms according whatever procedures your facility has in place for maintaining client information. The HIV/STD/TB Section will attempt to notify health care providers of the change via its website, a notice in the public health publication *CD Summary*, and a mailing of these FAQs to local public health departments. Nevertheless, all providers may not immediately become aware of the changes. If your laboratory doesn't want to continue to receive the forms, your might consider a separate attempt to communicate the changes to your own clients.

The revised version of Oregon Administrative Rule 333-018-0030 states that quarterly reports should begin March 1, 2007. Does this mean that the first reporting period should be December through February and that subsequent quarters will not coincide with calendar year?

No. The first quarterly report should be prepared for the period January 1 through March 31, 2007 and submitted sometime after April 1, 2007. With subsequent reports anticipated on or after July 1, October 1 and January 1.

What do the current changes have to do with reporting positive HIV antibody tests, viral loads and CD4 counts?

Oregon has made every effort to continually improve its HIV/AIDS reporting and surveillance systems. Improved systems help in identifying affected persons in need of services, guide prevention programs, and insure accurate monitoring of the HIV epidemic in Oregon.

Since 2001, Oregon Administrative Rule 333-018-0015 (http://arcweb.sos.state.or.us/rules/OARs_300/OAR_333/333_018.html) has required that all laboratories and medical providers report to their local public health authority or directly to THE HIV/STD/TB SECTION within one public

health working day, the name, date of birth, health care provider and contact information of anyone with a clinical test result indicative of and specific for HIV infection. Most commonly, these include confirmed (confirmed by Western Blot or IFA) antibody testing, p24 antigen tests, positive viral loads, and CD4 counts less than 200. This requirement has not changed.

In addition, since July 2006, licensed laboratories in Oregon have been required to report results of all viral load tests and CD4 lymphocyte counts, regardless of the test value (undetectable, detectable, normal, or abnormal) directly to THE HIV/STD/TB SECTION . This is mandated by Oregon Administrative Rule 333-018-0005, a copy of which can be found on the THE HIV/STD/TB SECTION website (http://oregon.gov/DHS/ph/hst/docs/3330180005PermSOSTextJan092007.pdf).

Do changes in laboratory HIV test reporting alter informed consent requirements?

Health care providers are still required to obtain informed consent. A provider signature confirming informed consent is no longer required. See Oregon Administrative Rule 333-012-0265 for detailed informed consent requirements. (http://arcweb.sos.state.or.us/rules/OARs_300/OAR_333/333_012.html)

When a patient is sent by an independent health care provider to have a specimen collected for HIV testing how should a laboratory ascertain the healthcare provider has obtained informed consent? Previously, OHD 49-03 was the proof of this.
Oregon Administrative Rule 333-012-0265 still says that "no person shall submit the blood of an individual to an HIV test without first obtaining informed consent or *ascertaining* that informed consent is obtained."

Laboratories are no longer responsible for verifying informed consent when a patient is referred for the test from an independent licensed health care provider.

How will revised Oregon Administrative Rule 333-018-0030 change data collection and consent documentation at sites receiving federal or state funding for HIV testing?

If your site receives federal or state funding for HIV testing, the Oregon State Public Health Division HIV/STD/TB Section (THE HIV/STD/TB SECTION) continues to require collection of individual testing data as a condition of funding. For the present, testing sites will continue to use the HIV-1 Test Request Form (OHD 44). The test provider is no longer required to sign the form. These completed forms can be submitted to the state laboratory along with the specimen, just as testing sites have been doing all along. A new version of the form might be created in the future. If you have additional questions about the use of the testing form in publicly funded sites, please contact the HIV Prevention

Program at 971-673-0153. A copy of the new rule is posted on the HIV/STD/TB Section website (http://oregon.gov/DHS/ph/hst/index.shtml).

HIV Test Reporting Changes in Oregon – Information for Blood Banks, Plasma Centers, Sperm Banks, Anatomical Gift Services, and Insurance Companies– January 30, 2007

Revised Oregon Administrative Rule 333-018-0030 does not affect plasma centers, sperm banks, anatomical gift services, and insurance companies. Reporting requirements have not changed. A copy of the new rule is posted on the HIV/STD/TB Section website (http://oregon.gov/DHS/ph/hst/index.shtml).