

September 13, 2016

SUBJECT: CONCISE EXPLANATORY STATEMENT FOR CHAPTER 246-338 WAC

The rule change amended chapter 246-338 WAC—Medical Test Site (MTS) Rules to add the Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) new regulation regarding patients having access to laboratory results; to add directed corrective action plan requirements for clinical laboratories in Washington that the Department of Health (department) regulates; and to update and clarify existing MTS regulations.

These adopted amendments enable the department to continue to adhere to federal standards applicable to all U.S. facilities that test human specimens for health assessment to diagnose and/or treat disease. All adopted amendments have been reviewed by CMS and have been approved as appropriate steps for the department to take to comply with federal regulations and CLIA guidelines.

In accordance with chapter 34.05 RCW—Administrative Procedure Act, the following describes the differences between the text of the proposed rule as published in the Washington State Register at the filing of the CR-102 and the text of the rule as adopted:

One non-substantive change was made to the adopted rules that differed from the text of the proposed rule per the following:

In section 090(9)(f)(v)(A) and 090(9)(vi)(A) in table 090-8, at adoption the most recent publication citation for the specific editions of CLSI documents was added.

In addition, one public comment was received:

“Upon a request by a patient or patient's personal representative, the laboratory may provide patients, their personal representatives, and those persons specified under 45 C.F.R. 164.524(c)(3)(ii), with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. I suggest adding language that hospital based laboratories may utilize the hospital health information management process for release of laboratory records. For teens, there are rules surrounding what information is protected and may not be released to their guardian.”

The department considered this comment and determined the suggested change is isolated to a small subset of laboratories only. Consequently, the department did not accept the recommended change.

Any questions regarding this rule adoption should be directed to Susan Walker, Program Manager, by telephone at (253) 395-6745, by fax at (253) 395-6365, or by email at susan.walker@doh.wa.gov.