



HAWAII HEALTH SYSTEMS
C O R P O R A T I O N

"Touching Lives Every Day"

COMPLIANCE ALERT 11-17

Proposed CMS Rule: CLIA Program and HIPAA Privacy Rule: Patients Able Upon Request to Lab Results from Laboratory

The Department Health and Human Services/CMS has issued a proposed rule that would allow patients greater access in requesting lab results directly from the laboratory. CMS feels this rules will provide patients great involvement in their healthcare.

Summary: According to proposed rule published today, "the proposed rule would retain the existing provisions that provide for release of test reports to authorized persons and, if applicable, the individuals (or their personal representative) responsible for using the test reports and, in the case of reference laboratories, the laboratory that initially requested the test. In addition, this proposed rule would also amend the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to provide individuals the right to receive their test reports directly from laboratories by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information."

According the American Hospital Association 9/12/11 "News Now" press release, the new rule... "would require clinical laboratories to release laboratory test results, including results in electronic form, to patients or their representatives on request. In addition, the rule would eliminate an existing exception to the Health Insurance Portability and Accountability Act's privacy rule for labs regulated under the Clinical Laboratory Improvement Amendments of 1988, and preempt state laws governing patients' direct access to lab result reports." Currently there are many states that have laws addressing the release of lab results; these laws would be affected by this proposed rule.

Proposed Rule Details: The full text of the proposed rule is found on:

[http://www.ofr.gov/\(X\(1\)S\(cp53mc3sjd3cbdfu4r32fhcj\)\)/OFRUpload/OFRData/2011-23525_PI.pdf](http://www.ofr.gov/(X(1)S(cp53mc3sjd3cbdfu4r32fhcj))/OFRUpload/OFRData/2011-23525_PI.pdf)

Persons desiring to make formal comments have 60 days to provide comments electronically or by mail. Details are for comment submission are listed on page 2 of the proposed rule.