Patient Direct Access to Lab Results

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In 2011, CMS, CDC and the HHS Office for Civil Rights jointly proposed a rule requiring clinical laboratories covered under CLIA and HIPPA to directly report test results to patients upon request. This proposal was prompted by the HHS Health Information Technology Policy Committee's review, which concluded that under current CLIA and HIPPA regulations, patients might be discouraged from taking a more active role in their personal healthcare decisions. HHS director Kathleen Sibelius made the announcement at the inaugural HHS Consumer Health IT Summit, stating, "When it comes to health care, information is power. When patients have their lab results, they are more likely to ask the right questions, make better decisions and receive better care."

The new standards would preempt states' direct access laws and regulations that restrict patients' direct access to lab results and establish a national standard for such access. This change has not been finalized, and it is unclear when or if it will be, but many expect a formal proposal by the end of the year with a 60 day comment period following release. Currently, seven states and the District of Columbia allow the direct reporting of lab results to patients, 13 states prohibit such notification, seven allow it with the health care providers' approval, and 23 states lack laws addressing the issue.

From a patient's perspective, improved access to laboratory results may empower patients to more actively enter into a partnership with the healthcare provider by facilitating follow up, ensuring that abnormal test results are not missed or ignored, thus alleviating anxiety associated with long waits for laboratory results.

Patients clearly would like to be informed about test results, both normal and abnormal in a more timely manner, and prefer that it be done by telephone in the case of abnormal results (1). It is not clear as to how patients will know what to do with the information. It is expected that laboratories will have basic information about test results, but it seems unlikely that they will offer any individualized interpretation. Furthermore, it seems likely that patient anxiety related to abnormal test results taken out of context could be more stressful than waiting for a physician call and interpretation. Many questions remain regarding potential impact on the doctor/patient relationship and shifting roles for assuming responsibility for tracking abnormal results. It is conceivable that as these relationships evolve, the net result might be less certain follow up. Unfortunately, there is very little data available to help guide the process.

Physicians are more ambivalent about allowing patients direct access to their laboratory results than are patients, gauging by public comments to the proposed rule and by opinion pieces in

medical journals. Physicians do recognize that patients have a right to their medical information. There is also the hope that providing that information will allow patients to be more engaged, to be better partners, to be more compliant in their care.

Allowing patients to see their lab results also serves as an additional method to insure that there is adequate follow up of abnormal results. It has been estimated that at least 8% of abnormal results are missed by physicians and that figure may actually be as high as 26%. (2) This obviously has serious liability implications for physicians.

On the other hand, patients do not have the education to place results in context. It is likely they will become anxious over abnormal results that are clinically trivial or not alert to seemingly normal results that might be abnormal for them. This concern is magnified in the case of highly sensitive results, such as HIV and genetic tests, for example. Physicians, or their surrogates, will need to educate patients proactively on the meaning of tests and will have to be readily available to interpret test results, both normal and abnormal, in a timely manner. While this is desirable in many ways, it will require reordering and reorganization of physician work flow, a process that is difficult in today's already stressed health care system under our current reimbursement mechanisms. It would be simpler as part of more organized care, such as in Patient Centered Medical Homes, which are structured for and compensate for care coordination.

With the proposal to allow patients direct access to their laboratory results, the government is seeking to impose yet another unfunded mandate on our health care system, another change in a time of near-revolutionary transformation. While the intentions are good, and the results may be more positive than negative, there is no convincing empirical evidence that patient care and clinical outcomes will improve. The proposed time to implementation is short (240 days after the final rule is published) (3), perhaps too short to prepare the groundwork to maximize the potential benefits and minimize the potential damage of this new CMS initiative. And a number of unresolved issues remain, such as use of the information by third parties for health care. Nevertheless, some form of this rule seems inevitable and we have to be as prepared as possible for its implementation.

1. Grimes GC, Reiss MD, Budati G, Gupta M, Forjuoh SN. Patient preferences and physician practices for laboratory test results notification. J Am Board Fam Medication. 2009;22(6):670-676

2. Giordana, T.D., Singh, H. *Should Patients Get Direct Access to Their Laboratory Results?* JAMA 2011: 305, 2502-3.

3.http://www.acla.com/sites/default/files/ACLA%20comments%20on%20HHS%20proposed%20rule%20on%20patient%20access%20to%20test%20results_1_1.pdf.