

PROFESSION

HHS wants to give patients test results straight from lab

Some physicians say the change could come at a cost, because the information would be delivered without the context of an explanation.

By KEVIN B. O'REILLY, *amednews* staff. *Posted Oct 3, 2011.*

Proposed changes to federal regulations would override existing laws in 20 states and give patients access to laboratory test results without having first to talk with the physicians who ordered the tests.

The Dept. of Health and Human Services said its proposal, announced in September, could enable wider deployment of personal health record systems and give patients more control over their health care information. Yet some physicians say the changes could come at a cost, because life-altering test results delivered without the context of a doctor's explanation may increase patient anxiety and degrade the physician-patient relationship.

In 13 states, labs are forbidden from sending test results directly to patients, according to HHS. The results must go to the ordering physician or another authorized health care entity. Seven states allow labs to send test results to patients, but only with the approval of the ordering physician.

Twenty-three states do not have laws governing patient access to test results from labs. Seven states, as well as the District of Columbia and Puerto Rico, say patients can obtain test results directly from labs without physician consent.

Under the Health Insurance Portability & Accountability Act, patients have the right to copies of all of their medical records. But the federal law governing clinical labs does not explicitly authorize the firms to send test results to patients. The proposed rule is intended to set a national standard to clarify the matter and help speed "meaningful use" of electronic medical record systems.

"When it comes to health care, information is power," said HHS Secretary Kathleen Sebelius. "When patients have their lab results, they are more likely to ask the right questions, make better decisions and receive better care."

Physician organizations have yet to weigh in on the rule, for which comments must be submitted by Nov. 14. The American Clinical Laboratory Assn., the trade group for diagnostic-testing firms, also declined to discuss the proposal.

HHS estimates that the rule will affect more than 22,000 labs, 6.1 million tests and impose \$56 million in laboratory compliance costs.

Quest Diagnostics, the world's leading lab-testing company, lauded the proposal and said it would recognize patients' right to their health care data.

"If you have your blood drawn, who owns that result?" asked Jon Cohen, MD, chief medical officer at Quest. "We believe it's you, the patient. It's your blood, your data, your results."

In 2010, Quest unveiled Gazelle, a free smartphone app to help patients manage their health information on the go. Users who live in the states where lab results can be sent directly to patients also can access them through the app. To protect confidentiality, patients must answer questions to verify their identity. The same verification process is outlined in the HHS proposal.

"What the rule does is level the playing field," Dr. Cohen said. "Now, in every state you can release results directly to patients."

Handling sensitive results

Quest first sends test results to physicians. Only after 48 hours are they sent to patients. The company does not send patients test results that are related to HIV, genetics or show a pathological diagnosis of cancer.

The company's approach to sharing test results with patients may not be reflected in the new federal regulations. As written, the proposal does not specify a waiting period before sending test results to patients and does not declare that any kinds of tests or particular findings should go through a physician.

Even doctors who favor giving patients access to test results have reservations about giving them immediate access to all test results upon request. In the last five years, the 3.5 million patients using Kaiser Permanente's personal health record portal have viewed more than 50 million test results, said Kate Christensen, MD, medical director of the health system's Internet Services Group.

"Ninety-nine percent of the time, it's a good thing for people to get the information [through the portal], but

sometimes it can be very upsetting, and there could be better ways to learn that information," said Dr. Christensen, a hospice physician in Martinez, Calif. "There are also cases when it really can do harm. For example, in some folks undergoing genetic tests you really need to be there in person to be ready to counsel the person and do a crisis intervention."

Kaiser Permanente typically gives physicians three to five days to view results before making them available to patients, Dr. Christensen said.

The OpenNotes Project is a portal that allows patients to access their medical records, view test results and see physicians' notes. It is being used by Beth Israel Deaconess Medical Center in Boston, Geisinger Health System in Pennsylvania and Harborview Medical Center in Seattle. Even this highly transparent system delays patient access to x-ray and pathology results to give doctors a head start, said Tom Delbanco, MD, leader of the project and professor of medicine at Harvard Medical School.

Physician practices and hospitals will have to adjust to the new rules, he said. "It may be that the patient sees disastrous news before the doctor can talk to them. The big downside is, 'Oh, the cancer is back and I've not even heard from my doctor.' Hopefully, we can put systems into place whereby doctors will get urgent calls from the labs when they get very abnormal results to say, 'Please be aware of this and talk to your patients.' "

Safety impact

There could be a safety advantage to patients being notified directly of their test results, Dr. Delbanco said.

"One of the comments we've received from doctors using OpenNotes is that it makes them feel much safer because there's another set of eyes -- the patient's," he said. "The missed test that winds up being a lawsuit for the doctor may be picked up in plenty of time. So there's very much a good side to this. Patients should be part of the safety equation."

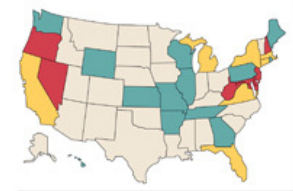
Other physicians said the HHS proposal could worsen the problem of poor communication over test results. Physician practices fail to inform patients of abnormal results about 7% of the time, according to a June 22, 2009, *Archives of Internal Medicine* study of more than 5,000 patient records at 23 primary care clinics.

"Does this create a more reliable system or does this create more noise?" asked Gordon D. Schiff, MD, associate director of the Center for Patient Safety Research and Practice at Brigham and Women's Hospital in Boston. "This gives a false sense of security, and it defuses responsibility. Is it the provider's responsibility to get the test results, or is it the patient's responsibility? It's better to have one reliable system than two halfway systems."

ADDITIONAL INFORMATION:

Varying access to lab results

How and whether patients are allowed to access their test results from clinical laboratories depends on the state or jurisdiction where the tests are performed. If rules proposed in September by the Dept. of Health and Human Services are adopted, patients across the country would have the right to obtain their lab results without physician approval.



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Lab results are sent only to physicians or authorized health care entity: Arkansas, Georgia, Hawaii, Illinois, Kansas, Maine, Missouri, Pennsylvania, Rhode Island, Tennessee, Washington, Wisconsin, Wyoming

Lab results may be sent to patients with physician approval: California, Connecticut, Florida, Massachusetts, Michigan, New York, Virginia

Lab results may be sent directly to patients without physician approval: Delaware, Maryland, New Hampshire, New Jersey, Nevada, Oregon and West Virginia, the District of Columbia and Puerto Rico

No state law governs patients' access to lab results: Alabama, Alaska, Arizona, Colorado, Idaho, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Montana, Nebraska, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, Vermont, Guam, Northern Mariana Islands and the Virgin Islands

Source: "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports: A Proposed Rule by the Centers for Medicare & Medicaid Services," *Federal Register*, Sept. 14 (www.federalregister.gov/articles/2011/09/14/2011-23525/clia-program-and-hipaa-privacy-rule-patients-access-to-test-reports)

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"CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports: A Proposed Rule by the Centers for Medicare & Medicaid Services," *Federal Register*, Sept. 14 (www.federalregister.gov/articles/2011/09/14/2011-23525/clia-program-and-hipaa-privacy-rule-patients-access-to-test-reports)

Gazelle, Quest Diagnostics' smartphone app (mygazelleapp.com)

"Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results," *Archives of Internal Medicine*, June 22, 2009 (archinte.ama-assn.org/cgi/content/abstract/169/12/1123)

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