Put It on the Board, 8/14

Labs grapple with handing results directly to patients

August 2014—Time is running short for laboratories to figure out how they will comply with a federal regulation that for the first time requires all U.S. labs to give patients their test reports within 30 days of request.

With the Oct. 6 deadline for complying with the mandate fast approaching, leaders at two laboratories shared how they are wrestling with the regulation during a July 31 webinar hosted by G2 Intelligence.

A process that at first blush may seem fairly straightforward—patient requests test results, lab hands them over—gets complicated fast. How does a patient request the test reports? How does the lab that conducted the test verify the identity of a patient, or of a patient proxy, who may live in another state? And how should labs handle patients' access to sensitive test results relating to sexually transmitted infections, or life-changing diagnoses?

The new regulation—which preempts contrary laws in 13 states and fills the gap in 23 states that had no statutes addressing patient access to lab results—is aimed at empowering patients and resolving a long-simmering tension in federal law. While HIPAA gave patients a federal right to copies of their medical information, CLIA '88 said that test reports could be shared only with authorized providers. Under the patient-access rule, published Feb. 6, labs must give patients their completed test reports within 30 days of their being requested. The federal regulation also requires that laboratories "take reasonable steps to verify the identity of the individual making a request for access," but does not spell out a precise form of authentication.

Giving test reports directly to patients represents a dramatic departure for lab medicine, said Marguerite Busch. She is vice president and chief compliance officer at Pathology Associates Medical Laboratories (PAML), a full-service reference lab in Spokane, Wash.

"For many of us who have been part of the laboratory industry for years and years . . . we would never release test results to the patient, or think that they should have them, that they would understand them, or that they would react correctly," Busch said. "This, even philosophically, is a big leap for many of us."

Even so, PAML has had a head start on many other labs around the country. Since 1993, Washington state law has allowed patients access to their medical records, including their lab results. Busch said PAML gets about 50 to 60 patient inquiries about copies of test results weekly. The lab's policy has been to require patients to show up in person to make the request, and bring a government-issued photo ID for authentication. Once patients hear that, only about 10 to 15 follow through each week.

But that patient-request process will have to change because of the new regulation, Busch said.

Busch

"You cannot make it so cumbersome or so difficult that the patient can't figure out how to make the request, or so difficult that they are unlikely to go through all the different steps," she said. "To us, that means we can no longer require that a person show up in person with a picture ID to get that report. Our lab now has many sites across the nation, and we may not have service centers there."

First, Busch said, patients must be informed about how they can request their test reports. She suggested that the request form—a Web link will suffice for most patients—ask for all the information a lab will need to find the test reports at issue and verify the patient's identity.

"Authentication of patients' identity is probably going to be our biggest challenge," Busch said.

A "secure patient portal is the best solution" for verifying patients' ID, but that is not yet universally available, she added. PAML is exploring whether to require that patients who live far away from one of its service centers have their request signed by a notary public in their communities for identity authentication. The lab already has used Apple's FaceTime video conferencing service to verify a patient's ID. The patient held up the photo ID next to her face, and a staffer felt comfortable confirming the identity based on that.

PAML also is considering whether to comply with requests when patients verify their identities by providing numerous details that only they are likely to have. That is the patient-authentication approach that will be used at American Pathology Partners (AP2), a Brentwood, Tenn.-based network of subspecialty anatomic pathology labs.

That information will include the patient's first and last names, date of birth, address, phone number, the ordering clinician's name, the clinician's group name and address, and the date of service and test reports requested. If the patient is making the request, a copy of the photo ID will be sought to verify that it matches other information provided, such as the patient's home address. If a patient representative is seeking the test reports, notarization must be included with the request, said Bill Tilton, AP2's senior vice president of operations.

The company's customer-service department will be given a script for how to handle patient requests, and no requests will be fulfilled until AP2 has confirmed that the ordering clinician has received the test reports at issue. PAML did not specify plans for a similar policy of withholding results from patients until clinicians have confirmed their receipt of them. Busch said the lab is considering a plan to delay sharing test reports with patients until 48 hours after the results have been released to ordering clinicians. For test reports deemed sensitive, there will be a 21-day waiting period after requests to ensure that clinicians have the opportunity to get the results and discuss them with patients.

Both AP2 and PAML will decline requests to receive test reports by email, unless the requesters agree to accept them in an encrypted format. The labs' leaders said patients will be encouraged to seek the test reports directly from their ordering clinicians as the most expeditious method.

For AP2, the overarching goal is to give patients access to their results in as seamless a way as possible while maintaining solid relations with clinicians.

Tilton

"We wanted to make sure that we weren't, in any way, complicating or disrupting a very successful report-delivery mechanism when we are servicing our physician customers directly," Tilton said.

As labs consider how they will comply with the patient-access rule, the $63 million question is how often patients will make these kinds of requests. That sum is the HHS estimate of how much it would cost annually for labs nationwide to comply with the rule if one in every 200 patients makes a test-report request. If only one in 200,000 asks for test reports, the nationwide tally for labs is tabbed at $3 million.

Neither AP2 nor PAML plans to charge patients for their test reports, as allowed under the rule. Busch, however,

said PAML may consider billing a patient who makes a sweeping request—a decade's worth of test reports, for example.

Busch said she is "not expecting a huge influx of requests" this fall.
"I don't think the average patient, or the average member of the public, is even aware of these changes in the regulations," she added. "But you need to be prepared." *—Kevin B. O'Reilly*

FDA's LDT framework draws mixed reviews

The FDA has notified Congress that it will issue draft guidance on laboratory-developed tests. As part of that notice, the FDA outlined a risk-based framework for regulating LDTs that would be phased in over several years.

"The agency's oversight would be based on a test's level of risk to patients, not on whether it is made by a conventional manufacturer or in a single laboratory, while still providing flexibility to encourage innovation that addresses unmet medical needs," Jeffrey Shuren, MD, director of the FDA Center for Devices and Radiological Health, said in a statement.

Laboratories would have to notify the FDA of all their LDTs—except those used in forensics and histocompatibility—and file adverse event reports related to them, said the agency's July 31 document, which is available at http://j.mp/ldtnotice.

Tests deemed to be low risk would not be required to get premarket review. This category includes LDTs for forensics, histocompatibility, rare diseases, those performed using class one devices, or tests for which there is no equivalent FDA-approved or cleared device. Traditional LDTs—those used at a single institution in the care of a patient and that require nonautomated interpretation—also would fall into the low-risk category.

High-risk LDTs would include tests performed with class three devices, and these would have to meet premarket review requirements within one to four years of the FDA's guidance being finalized. Premarket review for moderate-risk LDTs performed on class two medical devices would start in five years, after the high-risk reviews are done.

The FDA's tiered, risk-based framework is similar to the oversight approach the CAP outlined in April 2010. The College's regulatory model (http://j.mp/cap-ldtapproach) seeks "targeted FDA review and approval of clinical claims for only high-risk LDTs, with oversight of compliance by laboratories performing high-risk LDTs by CMS and CMS-deemed accreditors."

The CAP has discussed its oversight proposal with the FDA and will continue to engage with the agency and key stakeholders. It will detail its advocacy on the matter in future editions of "Statline."

AdvaMedDx voiced support for the FDA's harder line on LDTs. "FDA oversight of higher-risk diagnostic tests, including companion diagnostics, regardless of the manufacturer, is essential to patient safety," AdvaMedDx executive director Andrew Fish said in a statement.

Other stakeholders expressed reservations about the agency's impending action. American Clinical Laboratory Association president Alan Mertz said in a statement that LDTs should be addressed under the CLIA '88 regulatory framework "rather than impose an additional layer of regulation." Similarly, AMA board chair Barbara L. McAneny, MD, said in a statement that new regulatory requirements "may result in patients losing access to timely, life-saving diagnostic services and hinder advancements in the practice of medicine."

The Association for Molecular Pathology, meanwhile, has said that lab-developed tests ought to be considered medical procedures instead of being regulated the way the FDA oversees other tests.

"We are deeply concerned that attempts to regulate providers of these vital medical services as manufacturers will harm patients by reducing access, decreasing innovation, and substantially raising the costs of essential diagnostic testing," Roger D. Klein, MD, chair of the AMP's Professional Relations Committee, said in a statement.

The FDA will release its draft guidance sometime after Sept. 29. The public will have a chance to comment and the agency indicated that a public hearing will be held before final guidance is published. *—Kevin B. O'Reilly*