Put It on the Board, 3/14

Patient-access rule creates opportunities, costs for labs

A long-awaited Department of Health and Human Services rule that requires laboratories to provide completed test reports to patients upon request may strengthen the relationship patients have with their pathologists, but also will pose another compliance burden for labs in many states.

The rule, first proposed in September 2011, was finalized Feb. 6 in the Federal Register ("CLIA Program and HIPAA Privacy Rule: Patients' Access to Test Reports"). CLIA-regulated labs that do business with health plans must start complying with the rule Oct. 6, and the regulation will preempt contrary laws in 13 states and fill the gap in 23 states with no report-access laws, the HHS says.

When labs get requests from patients or their personal representatives—someone with a health care power of attorney for the patient, for example, or a child's guardian—they will be required to hand over completed test reports within 30 days. Labs will not have to provide patients with interpretation of the test results or make the presentation more patient-friendly, though they are free to do so.

Laboratory experts hope the new federal regulation will help make more conspicuous the role of pathology and the lab within medicine, and forge a stronger bond between pathologists and patients.

"Pathologists have been talking, as long as I've been in the field, about a new and special relationship with patients. There are lots of people complaining that we're always in the background," says Bruce A. Friedman, MD, active emeritus professor of pathology at the University of Michigan Medical School. "Well, this is an opportunity for pathologists to create a one-to-one relationship with patients."

How precisely pathologists would pursue that relationship remains unclear, even in Oregon and the six other states where patients already had a legal right to obtain their test reports directly from labs before the new federal regulation. Seven other states allowed labs to share test reports with patients only if the ordering clinician approved.

"Many feel there is an opportunity here for pathologists to use their expertise to establish patient contact and provide a valuable service," says Mick Scanlan, MD, vice chair of laboratory medicine at Oregon Health and Science University. "The logistics of doing this are not well worked out at this time."

Paul Epner, president of the Clinical Laboratory Management Association, also sees an upside to the patient-access rule.

Epner

"I do really like the fact that the lab becomes more visible to patients," he says. "Those of us in the lab community have said we hate being buried in the basement and no one knows who we are. Now we may be a little less buried."

Along with that increased prominence for labs will come more work. As of 2012, only 30 percent of labs gave patients direct access to their clinical test results, said a data brief published this February by the Office of the National Coordinator for Health Information Technology.

No one knows how often patients will go straight to labs with requests for their test reports. In the HHS rule, regulators assumed that between one in 200 patients and one in 2,000 patients would call on labs for their results. Based on those assumptions, the agency estimates the nationwide cost for labs to comply with the rule could be as low as $3 million and as high as $63 million.

However frequently the requests are made, labs will have to ensure that they are giving the test reports to the correct patients. The rule says labs must "take reasonable steps to verify the identity of the individual making a request for access," but did not specify any particular form of verification.

That regulatory vagueness could make life tricky for labs, says Peter M. Kazon. He is a lawyer at the firm of Alston and Bird and serves as outside counsel for the American Clinical Laboratory Association, which supported the regulation's adoption.

"The rule says, Hey, you've got to make sure it's the right person, and you need to put procedures in place to make sure that happens. If a lab is in Washington, DC, and the patient is in Los Angeles, Calif., and the lab has absolutely no interaction with the patient—that's no small order," Kazon says.

The CAP, American Society for Clinical Pathology, and American Association for Clinical Chemistry lauded the final rule as a step that will empower patients.

"We are pleased that the HHS has expanded patient rights and access to laboratory records, while recognizing the vital role pathologists and laboratories have in patient health care," CAP president Gene N. Herbek, MD, said in a statement.

Despite the HHS rule, there remain impediments to direct pathologist-patient contact. A New York state regulation requires labs to direct patient questions about the meaning or interpretation of their test results to "the referring health services purveyor." In a Feb. 11 letter to New York State Department of Health commissioner Nirav R. Shah, MD, MPH, Dr. Herbek wrote that the state regulation—which appears to be unique among the states—is "based upon an anachronistic practice paradigm" and ought to be voided.

In 2011 comments on the proposed HHS rule, some physician organizations sought assurances that patients would be sent their results after ordering doctors received them. They also asked federal regulators to distinguish between routine matters such as lipid panels and tests for cancer, pregnancy status, or sexually transmitted diseases. But the HHS stuck to its guns, concluding in the rule that 30 days should be "ample time to ensure providers receive sensitive test reports before the patient and to allow providers to counsel individuals on the test reports."

Paris System for Urinary Cytopathology open for input

The American Society of Cytopathology and the International Academy of Cytology are inviting participation in an international effort to standardize the terminology for reporting urinary tract cytology specimens.

The two organizations are calling for responses to a series of online statements. The responses will guide those building the glossary of terms and the requisite criteria for the terminology.

The idea to create a standardized terminology originated with ASC members, led by Dorothy Rosenthal, MD, of the Johns Hopkins Department of Pathology, and Eva Wojcik, MD, of the Loyola University Stritch School of Medicine Department of Pathology. The idea was developed further last May by ASC and IAC members at the 18th International Congress of Cytology in Paris. The terminology under development is known as the Paris System for Urinary Cytopathology.

The Web site (http://tinyurl.com/urinarycyto) will be open for input until Sept 1.

NIH, industry, and nonprofits join forces

The National Institutes of Health, 10 biopharmaceutical companies, and several nonprofit organizations launched Feb. 4 a partnership to transform the model for identifying and validating the most promising biological targets of disease for new diagnostics and drug development.

The Accelerating Medicines Partnership, or AMP, aims to distinguish biological targets of disease most likely to respond to new therapies and characterize biomarkers. Through the Foundation for the NIH, AMP partners will invest more than $230 million over five years in the first projects, which focus on Alzheimer's disease, type 2 diabetes, and rheumatoid arthritis and systemic lupus erythematosus. The three- to five-year pilot projects in these disease areas could set the stage for broadening the partnership to other diseases and conditions.

NIH director Francis Collins, MD, PhD, said in a statement that meeting the challenge of the new opportunities in therapeutics is "beyond the scope of any one of us and it's time to work together in new ways to increase our collective odds of success." The data and analyses the partnership generates will be made publicly available to the broad biomedical community.

Test reduces false-positive rate of fetal aneuploidy detection

Authors of a study published Feb. 27 in the New England Journal of Medicine say their findings suggest that cell-free DNA testing merits consideration as a primary screening method for fetal autosomal aneuploidy.

In a direct comparison of noninvasive prenatal testing using cell-free DNA with standard prenatal aneuploidy screening in a general obstetrical population, Illumina's Verifi prenatal test significantly reduced the rate of false-positive results for the detection of fetal trisomies 21 and 18. The study also demonstrated that Verifi performs consistently well in all pregnant women, regardless of their risk level for fetal aneuploidy.

The prospective, multicenter, blinded study analyzed samples from 1,914 pregnant women at all risk levels for fetal chromosome abnormalities. The false-positive rate for detection of trisomy 21 with Verifi was significantly lower than with conventional standard screening (0.3 percent versus 3.6 percent, $P<0.0001$). For trisomy 18 also, Verifi demonstrated a lower false-positive rate when compared with standard testing (0.2 percent versus 0.6 percent, $P=0.03$).

The positive predictive values of the assay were 45.5 percent for trisomy 21 and 40 percent for trisomy 18, which "underscore the conclusion that assaying fetal DNA is a screening tool and not a diagnostic intervention," write Michael Greene, MD, and Elizabeth Phimister, PhD, of Massachusetts General Hospital, in an accompanying editorial.

Verifi and standard screening correctly detected all cases of trisomies 21 and 18.