

Results release: new steps under new rules?

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October 2021—Neither pathologists nor laboratories should panic over the new 21st Century Cures Act rules making laboratory results immediately accessible to patients, pathology leaders agree. Most laboratories already release results to electronic health records and those results are made available in patient portals, and the Cures Act will require little change in how labs send results to EHR systems. But the rules, which took effect April 5, do come with some complexities to navigate.

By passing the Cures Act in 2016, Congress aimed broadly to increase interoperability across EHR platforms and to ensure that patients have full, portable, and cost-free access to their health care information. Of most direct relevance to pathology is the Cures Act's information blocking or open notes rule, mandating that lab report narratives and pathology report narratives, along with six other categories of clinical notes, be available without delay to patients in different electronic formats, including smartphones and secure online portals.

The Cures Act requires that patients' anatomic pathology and clinical laboratory electronic test results that are available to clinicians also be immediately available to patients with limited exceptions, explains Jonathan Myles, MD, chair of the CAP Council on Government and Professional Affairs and a member of the CAP Board of Governors. But, he says, "There is no mandate for pathologists to develop new electronic reporting systems." In most instances, direct responsibility for compliance with this part of the Cures Act is in the health care organization's hands rather than the laboratory's. Pathologists will have at the very least several months to adjust to the new standards without fear of penalties—which, for purposes of results reporting by pathologists, are subject to future rulemaking and thus are not imminent this year.

Still, questions have swirled about exactly what effects the Cures Act reporting mandates will have on pathologists' decision-making and on day-to-day laboratory operations. Will patients be calling pathologists to discuss their results? How disruptive will it be for patients to receive sensitive results before having access to a clinician to explain them? What if state laws carry restrictions on release of particular results? Some important terms in the Cures Act, including "lab report narratives," "pathology report narratives," and "machine-readable format," have not yet been clearly defined, nor do the interoperability requirements define whether or how pathology and lab data should be provided in structured format.

The CAP has made it a priority to determine what it can do to mitigate the concerns members have about meeting the requirements, says Dr. Myles, who is an anatomic and clinical pathologist at the Cleveland Clinic. In meetings with the ONC—the Office of the National Coordinator for Health Information Technology, which is managing Cures Act implementation—it is clear that numerous groups have expressed reservations about the release of all results to patients immediately, in particular because of the risk of potential psychological harm. But, he adds, it's also clear the ONC has considered these reservations and the ONC believes at present that the benefits of immediate release outweigh the risks.

In most cases, *preliminary* results do not have to be made immediately available. If the preliminary results do not go into the medical record—for example, a draft report—and are not used in medical decision-making, they do not have to be released to the patient.



Dr. Walter Henricks (left) and Dr. Jonathan Myles of the Cleveland Clinic. Awareness and preparation, they say, should be the main response to the Cures Act results reporting requirements. [Photo by: Dale Dong]

Even more important, “there are several exceptions that can be applied in some instances to individual reports to prevent the immediate release of the report,” Dr. Myles says, such as a concern that it would violate patient privacy under HIPAA or cause patient harm. To use the preventing patient harm exception, the physician would have to document a reasonable belief that the delay in release will substantially reduce the risk of harm, and it must be limited to that specific instance. This is generally the responsibility of the ordering clinician, he says, but pathologists could invoke this exception on a case-by-case basis if the pathologist is aware of the circumstances of a specific clinical situation or was involved in a decision to order a test. “But if they did decide to delay release,” Dr. Myles says, “they would have to document, in some form that they could retrieve at a later date if they were audited, why the report was not made immediately available to the patient.”

The hitch with exceptions is that all of them have to be justified on a case-by-case, record-by-record basis. Blanket exceptions that would allow for the delayed release of results in all of a certain category of clinical or patient situations are not permitted under the Cures Act.

The lack of limited blanket exceptions is of concern to the CAP. Making exceptions only on a case-by-case basis “would be cumbersome to practicing physicians, and it would increase costs as well due to the increased administrative burden,” Dr. Myles says. For example, “In anatomic pathology, your ordering system may be able to be modified such that the provider at the time of ordering the test can prevent immediate release of results because the results would potentially cause harm. But if you don’t currently have that technology in place, there would be a cost involved in developing it.”

The CAP believes limited blanket delays for specific kinds of tests would reduce potential patient harm and improve care coordination. “Case-by-case exceptions sound good on the surface, but when you get into some of these

specific situations, it does make sense for patient care to allow some limited blanket delays. Some may be appropriate, and we're continuing to advocate for that at the CAP," Dr. Myles says.

Blanket delays could be imposed, for example, on any tests for which counseling is required or where unexpected results would trigger state regulatory prohibitions. In addition, release of adolescents' test results may be regulated according to their age. But as the person gets older, the rules on what can be released change, he explains. "Some types of results can be released to adolescents but not the parents, even if the parents have a proxy. And it's unclear if all health care electronic record formats can comply with these new situations."

A common worry among pathologists is how patient calls to the laboratory or the pathologist's office should be handled. But "there is nothing in the legislation or the rules that requires a pathologist to talk to the patient," Dr. Myles says. Although some CAP members have received calls from patients since the rule became effective, there does not appear to be a large increase in the number of such calls. However, the Cures Act provides pathology groups the opportunity to discuss among themselves how they would handle such calls, and this is something all pathology groups should discuss, possibly in consultation with the ordering physicians, Dr. Myles says. The CAP's advice for pathologists concerned about calls from patients is to develop a protocol for how to handle patient calls and to consider discussing the situation with the group's ordering clinicians to ensure there is a mutual understanding of how the calls will be handled.

Luckily, pathologists, clinicians, and laboratories have time to adjust to the new rules because there are no civil penalties for noncompliance of clinicians at present. Under the Cures statute, penalties will be set through the rulemaking process, so the normal rounds of proposed rule, public comment, and revisions will have to take place before there can be penalties. This delay will give organizations time to implement workable protocols.

Meanwhile, the CAP is advocating for changes. "The intention of the law was good. The CAP supports patients being more informed about their health care and more engaged in the management of their disease. However, the regulation needs to be fine-tuned to best serve our patients in the long run," Dr. Myles says.

Since many states already have rules on how lab results should be released to patients—in some cases prohibiting certain test results from immediate release—another potential concern is how such rules will mesh with the Cures Act rules. Some states, for example, require that counseling of the patient be provided at the time certain results are released. "Our understanding is that the Cures Act would not preempt state laws in that respect," he says.

Dr. Myles believes the important messages to pathologists about the Cures Act are: "You do want to get that result to the patient as soon as possible. And I would encourage pathologists to work with the health information system for their enterprise to have a policy in place on release of this information to the patient. The pathology group needs to talk in advance about how they are going to handle any patient calls, and it's important to interact with the medical staff of the hospital executive committee to discuss how the institution is going to deal with Cures requirements."

Some of the alarm about the new Cures Act standards is unnecessary, says Walter Henricks, MD, laboratory director and vice chair of the Pathology and Laboratory Medicine Institute at the Cleveland Clinic. "But there are legitimate concerns about the immediate release of results, and I agree 100 percent with concerns about how to comply. When this kicked in, there was real concern for labs and pathologists, so it's good that the College is looking for ways to help the membership understand and prepare."

Under federal policy, some health care organizations have been allowed to delay full implementation of immediate results reporting if they are in the process of making technological enhancements or changes, such as a system upgrade or implementation of a portal system. However, for pathologists and laboratories in general, the standards create more of a practice issue, not a large compliance issue, Dr. Henricks believes. "Clinicians are likely to receive more calls from patients who saw a test result before the clinician did. The clinician may not realize it wasn't the laboratory's choice to release it to the patient automatically" on a particular time frame. "Laboratories may need to prepare to explain to clinical colleagues that the timing of release of results is not the laboratory's decision because it's set by these new standards under the Cures Act."

Clinicians are busy, and “it may not have been obvious or front of mind for them what the implications were going to be,” Dr. Henricks says. “All of a sudden patients are getting results of everything immediately. We’ve heard more and more anecdotes about patients who find out a result on their phone from the EHR patient portal. Results are released to inpatients as well, so patients may have already seen their results by the time a medical team sees them on rounds.”

Release of routine lab results on a short time frame, whether immediately or within 24 hours, had previously become common in health care organizations, Dr. Henricks notes. Traditionally, organizations once had more discretion about releasing some results, such as surgical pathology results. “Even if there was an automatic release required, there was a wait time to give physicians time to see the result and contact the patient prior to release.”

But times have changed, and awareness and preparation should be pathologists’ main response to the new standards, he says. “The best preparation is to be aware of what is occurring and why, and any nuances in your specific organization’s approach to implementing the standards. Commercial laboratories and pathology practices small and large need to think, ‘Does our group need a policy on how much information to provide a patient who inquires about a result or report before they have communicated with their doctor?’ It’s a balance,” Dr. Henricks says, “between being helpful yet not wanting to potentially overstep and contradict the doctor who has the relationship with the patient.”

Once the Cures Act results reporting requirements went into place at the University of Washington, “there were definitely a couple of specific cases where providers contacted the lab—upset, or surprised at least—that their patient had received results ahead of their ability to discuss them with the patient,” says Noah Hoffman, MD, PhD, director of the Informatics Division and co-director of the next-generation sequencing and analytics laboratory, UW Department of Pathology and Laboratory Medicine.



Dr. Hoffman

“The main thing that we can and should do is not to think in terms of delaying results,” he says. “That’s the intention of the law, and the bottom line is that this is the way things are now.” Instead, he believes, pathologists should think in terms of preparing providers to understand the timing of release of results, and preparing patients to understand they may receive results before having an opportunity to talk with their providers.

The potentially panicked patient, receiving a result before the provider can talk with them, “isn’t something we’ve dived into” in the past, Dr. Hoffman says, pointing out that the laboratory can’t do much about the interface between providers and patients. “Something that is increasingly on our minds, however, is considering what a lay person would think when reading a laboratory result. Historically, we’ve been addressing these results to the provider, not the patient. Now we have to ask, what is our obligation to provide relatively interpretable results for a patient?”

The text of laboratory reports in anatomic pathology presents two distinct dimensions of problem. “Obviously, you’re going to use different language to describe results to providers and patients,” Dr. Hoffman says. When providers look at some results, they might say, “This is a completely uninterpretable wall of text. What’s the patient possibly going to do with this?” He doesn’t think the consensus is that every result necessarily needs to be geared toward the patient. “But we should be very sensitive that some words are scarier than others and that patients will be reading these. And we should do our very best not to use terminology that would be unnecessarily worrisome or confusing.”

"Maybe that doesn't call for a big, systematic review of our results," Dr. Hoffman continues. "But we are trying to be more sensitive to this as we are bringing new tests up and crafting the interpretations they need. Laboratories should understand that patients who will be reading this language may not be doing so in the context of a visit with the benefit of counseling or a discussion with their provider in advance."

It may be worthwhile, he suggests, for pathologists to put themselves in the position of a person without a physician's background and imagine what effect the wording of a particular lab result might have. "The lab is really the primary owner of the words that are coming out with the result, and we need to keep that in mind, now that our audience has grown. And then we should make an effort not to remove information that would be valuable to the provider but try as much as possible to frame results in a way that is the least confusing."

Will the new standards change pathologists' relationship with their telephones as patients contact them more often for explanation? Dr. Hoffman would be surprised if that happened, because it's not always obvious how to contact the lab. "Absolutely, providers should expect and have experienced additional calls, but mainly from caregivers. I don't think the lab is really in the crosshairs here. This is mainly a burden that will fall on providers."

A secondary objective of the Cures Act, he adds, might be to let patients be more likely to catch errors. He has seen situations where a patient will see their chart and say, "'Hey, this entry isn't right.' That happens a lot in the context of allergy lists and problem lists, but it can also happen in the context of laboratory and pathology results."

How much will pathologists need to change their practices to adapt to Cures Act requirements? "Historically," Dr. Hoffman points out, "the customer of the pathologist has been the physician who orders the tests. The primary intention of the lab report is to deliver information concisely in a provider-focused format. There really hasn't been a requirement for the lab to translate results for the patient. That's been the domain of the provider."

"And it's pretty far outside of what a lab, or at least academic clinical labs not in the business of direct-to-consumer testing, have historically provided as a service. The lab community has had a lot of conversations about the lab's own role in providing interpretive services to the provider," Dr. Hoffman notes. "As far as the laboratory's role in communicating results to the patient, I haven't heard that conversation as much, but it's a conversation we need to have."

In the Epic electronic medical record, he says, "The IT governance model is centralized. So the extent of the laboratory's involvement is going to depend on local institutional governance. And the majority of enterprises are going to have a pretty top-down implementation." Given that governance mode, he adds, "I think there will often be minimal direct involvement by the lab in the implementation" of new results reporting requirements. "Most often the lab is simply reporting into an EHR; there's no direct interface with the patient."

California is one state that set strong restrictions on the immediate release of certain test results long before the Cures Act, says Sue Chang, MD, vice chair of the CAP Professional and Community Engagement Committee and medical director of surgical pathology and interim chief of anatomic pathology at City of Hope, a cancer center in Duarte, Calif. In fact, the restrictions are the kind of blanket exceptions to the mandate to immediately release results that would be ruled out by the Cures Act. But as state restrictions, they can override Cures Act rules. "So we have complied with the Cures Act" rules on making lab results available to patients, "but with a wrinkle," Dr. Chang said in a May CAP webinar on compliance with the 21st Century Cures Act.

Under California law, disclosure of results to patients through Internet posting or other electronic reporting is largely prohibited for HIV antibody tests, for the presence of antigens indicating a hepatitis infection, for drugs-of-abuse tests, and for test results related to routinely processed tissues, including skin biopsies, Pap tests, products of conception, and bone marrow aspirations for morphological evaluation, if they reveal a malignancy.



Dr. Chang

These blanket restrictions will continue in place statewide, regardless of the immediate reporting requirements of the Cures Act. But the crux of the current discussion about how to coordinate the Cures Act with California code, Dr. Chang says, is the notion that “disclosure” refers to the first time the patient is informed of a test result. “The first notification not being electronic would imply that it can’t come from the medical record in an automatically released report before it is conveyed by a person, such as a doctor or nurse,” although she says this does mean that manual release must be allowed at an organizational level.

Interestingly, “the physicians can add a result comment that travels with the actual result to the patient’s portal,” Dr. Chang said in the webinar. “The physician can say, ‘I will talk about this result with you at next week’s appointment,’ for example. As a pathologist, when I open up these results, I can see any comments that the ordering provider has sent, which I have found to be really useful.”

City of Hope, Dr. Chang says, led an “open notes” initiative in mid-2019 to release certain types of outpatient notes to the patient portal. “We started with histories and progress notes, which included quotations or snapshots from pathology and laboratory results as well as imaging results. The result was fairly positive and this led the institution to expand the initial initiative to include some test results as auto-released to patients, including most ambulatory clinical laboratory tests on a slight time delay.” Germline testing results were blocked from release to the patient portal, as were some donor testing results—not only for confidentiality of bone marrow and blood donors but also because the test results were in a tabular format that does not translate well across the patient portal screen, she notes.

The Cures Act implementation may provide a good opportunity to change the format of pathology reports, Dr. Chang says, in part because enforcement through civil penalties or disincentives will not kick in for a while and experimentation is possible. For example, a question that has arisen often is whether pathologists should include disclaimers on pathology reports warning patients about potentially sensitive content. She thinks patients should be warned but perhaps not in individual results reports. “It should be before that, because in the whole medical record, the patient should be told there are things here that you may or may not be seeing for the first time, or something that you don’t think is accurate or don’t remember hearing. So anything in that chart may be news to you, not just the test result.”

The format of results reporting is sometimes not the friendliest, and reports sometimes don’t contain the diagnosis, Dr. Chang says. “But when people are making the effort to learn more, I think it’s our duty as physicians to help them understand their own health.”

“As has been said, we should never let a good crisis go to waste,” she said in the webinar. “Between COVID and the Cures Act, there’s never been a brighter spotlight on the laboratory. And for pathologists this might be the time for us to really use this motivation to redesign pathology reports to increase our exposure to our colleagues and to the leadership of our institutions.”□

Anne Paxton is a writer and attorney in Seattle.

For further details about the Cures Act and how to comply with it, see the CAP’s Cures Act information page at www.cap.org/member-resources/cures-act-information. A CAP Cures Act fact sheet is at documents.cap.org/documents/sharing-test-results-cures-act-fact-sheet.pdf.