COLLEGE of AMERICAN PATHOLOGISTS
Advocacy

CURES Fact Sheet:

New Federal Regulations on Patients Accessing their Health Information

CURES Act Interoperability Rules
Top Takeaways for Pathologists

1. Most pathologists do not have to change the way they report. Continue to report finalized reports from the LIS to ordering systems—with reasonable turnaround time. No need to change or add data elements for this rule.
2. Pathologists should not delay release of laboratory and pathology results until the ordering clinician's review. Decisions about delaying release of data is generally a decision of the ordering clinician in the context of their relationship with the patient. There are no blanket exceptions; only case-by-case exceptions for privacy, security reasons.
3. The rules do not specify that pathologists must take phone calls from patients. It is the pathologists' professional discretion on handling patient calls; for the most part, these calls cannot be billed within current payment policy.
4. The rules, which started to go into effect April 5, 2021, initially had a restricted definition of Electronic Health Information (EHI). However, after October 6, 2022, all EHI are subject to these rules. However, this does not substantially change any expectations for pathologists. The rules do not require a specific functionality or standard. Penalties *for clinicians* will not go into effect until there is further rulemaking. Lack of penalties gives organizations time to implement workable protocols.

Why?

So patients have easier access to their own health information.

The government continues to seek to make health data accessible and available to patients through different formats, including smartphones and web portals. The new data-sharing regulations went into effect with a limited definition of Electronic Health Information (EHI) April 5, 2021. After October 6, 2022, all EHI are subject to these regulations. These regulations are intended by the ONC to lay the groundwork for patients to have easier access to --and control of--their health information. The ONC states that patients should be able to access their health information from an app of their choice in a fully automated, low-cost manner.

What?

The ONC's rule requires all physicians to make their office notes, lab results, and other diagnostic reports available to patients as soon as the physician's office receives an electronic copy. D*ecisions about delaying release of data is generally a decision of the ordering clinician in the context of their relationship with the patient.* The rules have exceptions on a case by case basis for protecting patient privacy and security, but specifically does not allow for blanket exceptions.

Note: the Cures Act is different than the CARES Act
Cures Act requirements are about patients accessing their healthcare information. CARES act is COVID-related: reporting COVID test results to the appropriate health department.

The implications for pathologists are that test results should be shared are soon as they are finalized--generally with the ordering clinician and/or through a patient portal for direct patient testing. Thus, current reporting from laboratory information systems (LIS) to the ordering systems with reasonable turnaround time should satisfy the requirements without a need to change or add data elements.

FAQS

Impact on pathologists

Do pathologists have to change the way we report?
No.
Most pathologists currently share test results as soon as they are finalized—generally with the ordering clinician and/or through a patient portal for direct patient testing. Thus, current reporting from LIS to the ordering systems with reasonable turnaround time should satisfy the requirements without a need to change or add data elements.

Does this mean that laboratory and pathology results could be released prior to the ordering clinician's review?
Yes.
Organizations should not block patient access until a physician has a chance to review results. Organizations may be able to create a policy that enables physicians to consider the release of lab tests on a *case-by-case basis.* This becomes the responsibility of the ordering clinician, and the rules of the organization.

Can pathologists delay the release of results until the patient's ordering clinician has an opportunity to review the results?
Not in most cases.
The rules do not allow for blanket exceptions; case-by-case decisions are allowable for privacy and security purposes, and are usually made by the referring clinician based on the ordering clinician's relationship with the patient.

Do the new rules mean pathologists have to take phone calls from patients?
No.
The rules do not say that pathologists must take phone calls from patients. It is the pathologists' professional discretion on handling patient calls. Some organizations are developing communications to address this, including by the referring physician. We encourage pathologists to engage with referring practices and organizations on how patients should be educated about their results. Pathologists could also come up with a script to respond to such calls by suggesting that the patient contact the referring clinician, since the referring physician has more knowledge about what these results mean to this particular patient.

Can I bill if a patient calls me?
Not usually. For the most part, these calls cannot be billed within current payment policy.

Do pathologists have to share *incomplete* test results?
No.
Draft clinical notes and laboratory results pending confirmation are examples of data that may not be appropriate to disclose or exchange until they are finalized. However, if such data are used to make health care decisions about an individual then that data would fall within the definition of "designated record set" and subject to the rules.

Do pathologists have to directly send reports to all patients?
No.
The rules say that test results be made **available** immediately upon finalization. However, many pathologists already provide results through patient portals for direct patient testing.

Exceptions to information blocking

Are there information blocking exceptions?
Yes.
There are some exceptions in the regulation. However, there is no blanket exceptions. *The exceptions are situational and must be evaluated by the referring clinician, or in policy at the organization.*

If a pathologist chooses to invoke an exception, documentation is critical. The specific facts and circumstances associated with your decision to use an exception will be important to include in your documentation. Each act is evaluated on a case-by-case.

What is the Preventing Harm exception?
Information blocking necessary to prevent harm to a patient or another person, provided certain conditions are met.

Key conditions for this exception include: a reasonable belief that the practice will substantially reduce a risk of harm; the practice must be no broader than necessary; it must be an individualized assessment of the risk of harm.

Would the Preventing Harm exception cover a "blanket" several day delay in the release of laboratory or other test results to patients so an ordering clinician can evaluate each result for potential risk or harm associated with the release?
No.

Blanket delays that affect a broad array of routine results do not qualify for the Preventing Harm Exception. The Preventing Harm Exception is designed to cover only those practices that are no broader than necessary to reduce a risk of harm to the patient or another person.

The exception is made context of a clinician-patient relationship. In the context of that relationship, the clinician ordering a particular test would know the range of results that could be returned and could prospectively formulate, in the exercise of their professional judgment, an individualized harm determination for the specific patient.

Where the patient is a minor and to reduce a risk of harm can the precenting harm exception apply to parent or legal guardian's access to the minor's health information?

Yes, where the risk of harm has been determined on an individualized basis and is no broader than necessary. This is also usually at the discretion of the ordering clinician.

What is the Privacy exception?
Information blocking necessary to protect an individual's privacy.

Clinicians are not required to disclose health information in a way that is prohibited under state or federal privacy laws. Key conditions include (but are not limited to) respecting an individual's request not to share information.

Implementation and Enforcement

Are pathologists at risk of monetary penalties?

Not yet.

Penalties and other "disincentives" for physicians and all other health care providers have yet to be determined. Through the process of rulemaking, the ONC will determine penalties. This means that despite the rules already going into effect, and with the rules expanding on October 6, 2022, the lack of penalties gives organizations time to implement workable protocols.

When do the rules go into effect?

The rules went into effect April 5, 2021. However, the rules will expand to include all EHI on October 6, 2022. The expansion of these rules should not affect pathologists.

What should pathologists do?

- √ Continue to make final reports available electronically to the ordering clinician in a timely manner.
- √ Develop a script for potential patient phone calls that directs patients to the ordering clinician for interpretation of the results. Consider discussing the situation with your ordering clinicians to ensure you have a mutual understanding of how the calls will be handled.
- √ Check that the referring clinician's organization has policies and procedures in place for these new rules (ie, how will ordering clinicians make and document case-by case exceptions; what if the pathologist disagrees or has concerns about a specific patient). In circumstances such as genetic tests, adolescent health, mental health, and substance use disorder, physicians should consider how their organization's policies can incorporate important situational context each physician already uses in their day-to-day practice.
- √ Always consider what is best for the patient and ensure that organizational policies and procedures reflect this.

Are there resources to help me?

The ONC provides some information:
ONC's Information Blocking FAQs

The American Medical Association (AMA) has released a two-part educational resource to help physicians understand and comply with the information blocking rules:
Part 1: What is Information Blocking
Part 2: How do I comply with Information Blocking and where do I start?