Fact Sheet: New Federal Regulations on Sharing Test Results with Patients

Background
The 21st Century Cures Act (Cures Act) enacted in December 2016 sought to improve the exchange of health data and information between patients and their physicians, hospitals, and other health care providers. They must give patients access to their health care information, for example, through an electronic health record (EHR) system and not unreasonably block information. The Cures Act directs the Office of the National Coordinator for Health Information Technology (ONC) to identify activities that are reasonable and should not count as information blocking. Earlier this year, the ONC and the Centers for Medicare & Medicaid Services (CMS) finalized the information blocking and interoperability regulations to implement provisions of the Cures Act. Information blocking is defined broadly as any practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI) when the entity knows it is likely to do so.

How do pathologists comply with the new rules on sharing test results?
For pathologists, they typically comply with the regulations by sending pathology reports and laboratory results through the laboratory information system (LIS) to the ordering physicians’ Certified Electronic Health Record Technology (CEHRT) systems. The ONC’s rule requires all physicians to make information available to patients as soon as the physician’s office receives an electronic copy. While pathologists are responsible for providing laboratory and diagnostic results to their organization’s EHR, the responsibility for sharing this information through a patient access application programming interface (API) lies with the organization’s CEHRT. So, while the rules may not apply directly to pathologists, they may face repercussions from their organizations if they delay sharing results.

Do pathologists have to directly send reports to all patients?
No, this regulation does not require pathologists to directly release test results to patients. The regulation only addresses that test results be made available immediately upon finalization. The 2014 Patients’ Access to Test Reports addresses the release of test results directly to patients.

Are there any exceptions to information blocking?
Yes, there are some exceptions in the regulation. However, there is no blanket exception that states that certain rules do not apply to pathologists. The exceptions are situational and must be evaluated on an institution-to-institution basis. The ONC uses the term “exception” to implement a concept of reasonable and necessary activities used in the Cures Act. The ONC has defined eight exceptions to information blocking that can be found on the ONC’s website. A major component of a physician’s compliance with information blocking, and use of exceptions, is documentation. The specific facts and circumstances associated with your decision to use an exception will be important to include in your documentation. Moreover, failing to meet the conditions of an exception does not automatically mean a practice is information blocking, only that there is not guaranteed protection from penalties or disincentives. Each act must then be evaluated on a case-by-case.

What is the practical impact of these new regulations?
Pathologists and their pathology departments or groups should take part in and lead discussions about how the new regulations apply to them and which circumstances will meet reasonableness standard for an exception. With the information from pathology reports more readily available, patients may have questions about test results and call pathologists for an explanation or more information.
Can I bill if a patient calls me?
The CAP is in the process of determining the effects of the regulations and it is unclear if pathologists can bill a service for discussing test results.

How can a physician be considered an “information blocker” and how can pathologists prepare to comply with the new rules?
To be an information blocker, the law states that physicians must know that an activity or practice is unreasonable and likely to interfere with, prevent, or discourage access, exchange, or use of EHI. Pathologists should work closely with their organization to determine the organization’s reasonableness standard to comply with the regulations. According to the American Medical Association (AMA), developing and documenting scenarios where physicians may or may not take reasonable actions could assist in compliance audits. Procedures should provide a detailed workflow where case-by-case findings will be documented and by whom. While a company-wide policy blocking patient access until a physician has a chance to review results would likely implicate the information blocking provision of the ONC’s rule, organizations should consider whether a policy can be created that enables physicians to consider the release of lab tests on a case-by-case basis. Such policy may take into account the physician’s relationship with the patient, context of the reason for the lab test itself, who other than the patient may have access to the test results, and their medical specialty’s guidelines around the release of information. Consider how a physician would document their decision to restrict access to information in accordance with their organization’s policies and their profession’s guidelines. While the Harm Exception does not allow physicians to use their concern for a patient’s emotional harm as a reason to restrict access, how would a physician document—using their professional judgment—that their actions were reasonable given the circumstances?

Is a delay in release of laboratory tests until after physician review considered information blocking?
Many physician organizations restrict patient access of some laboratory results or other diagnostic reports before a physician has an opportunity to review the result. Often there is a 36- to 48-hour window between patient access and when physicians have a chance to review. However, the ONC’s regulations define information blocking as an action by an actor [physician] interfering with, preventing, or materially discouraging access, exchange, or use of EHI. Slowing or delaying access, exchange, or use of EHI could constitute an “interference” and implicate information blocking. Physicians who have the capability to provide a patient same-day access to their results, but take several days to respond, would likely be considered information blockers. However, always consider what is best for the patient and ensure your organizational policies and procedures reflect this. Also consider how your organization’s policies and procedures could incorporate the Harm Exception for these situations.

What are penalties for information blocking?
EHR vendors can receive up to $1 million in civil monetary penalties per violation. Penalties and other “disincentives” for physicians and all other health care providers have yet to be determined. However, physicians participating in the Promoting Interoperability (PI) Program could see an impact to their CMS Merit-based Incentive Payment System (MIPS) incentives if they are found to be information blockers. Since pathologists are exempt from the PI category of MIPS as non-patient facing clinicians, they will not be penalized in MIPS.
When do the rules go into effect?
The new deadline to comply with the rules, which are required by the 21st Century Cures Act (Cures Act), is now April 5, 2021, giving pathologists and laboratories more time to become familiar with requirements.

Where can I find more information?
ONC Fact Sheets
ONC Webinars
What ONC’s Cures Act Final Rule Means for Clinicians and Hospitals
ONC's Information Blocking FAQs
AMA's Information Blocking Guide Part 1
AMA's Information Blocking Guide Part 2