



COLLEGE of AMERICAN
PATHOLOGISTS

Key Take-Aways for Compliance

The 21st Century Cures Act

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May 6, 2021

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Topics for Today's Discussion

- Basic requirements of the new Cures Act interoperability rules and key take-aways for pathology practices.
- Opportunities for exceptions to the rule and how to address pathologist concerns for patient harm in release of results.
- Insights into how various organizations are implementing provisions of the new Cures Act interoperability rules.
- Discussion: practical steps pathologists can take to ensure they are in compliance with the new rules.

Disclaimer

The information presented today represents the opinions of the panelists and does not represent the opinion or position of the CAP.

This should not be used as a substitute for professional assistance.

Stephanie Peditto, Sr. Director of Quality

- **Oversees**
 - **CAP's Pathologist Quality Registry**
 - **CAP's Measures Portfolio**
 - **Quality Payment Program Advocacy**
 - **Scientific Regulatory Policy**



Goal of Cures Act and Interoperability Rules

- **Make it easier for patients to access -- and control -- their own health information**
- **Make health data accessible and available to patients through different formats, including smartphones and web portals.**
 - **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.**

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.

Overview of Interoperability Requirements

- **Went into effect April 5, 2021**
- **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**
- ***Decisions 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**

Exceptions to Information Blocking

- **Preventing harm exception**
 - Necessary to prevent harm to a patient or another person, provided certain conditions are met
- **Privacy exception**
 - Necessary to protect an individual's privacy
- **No blanket exceptions**
 - *Exceptions are case-by-case and situational and must be evaluated by the referring clinician, or in policy at the organization*
 - *Generally at the discretion of the ordering clinician, based on the clinician-patient relationship*

Cures Act Interoperability Rules Top Takeaways for Pathologists

- ✓ Most pathologists do not have to change the way they report
- ✓ Pathologists should not routinely delay release of laboratory and pathology results until the ordering clinician's review
- ✓ The rules do not specify that pathologists must take phone calls from patients. It is the pathologists' professional discretion on handling patient calls.
- ✓ The new deadline to comply with the rules is now April 5, 2021, but penalties *for clinicians* will not go into effect until there is further rule-making

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CAP Has Actively Advocated with ONC About Challenges With Cures Implementation

- Reduce potential patient harm and improve care coordination by allowing some limited blanket delays for specific kinds of tests
 - Allow a delay for the opportunity for involved clinicians to create an integrated response before patient communication for the best care coordination
 - Burden of asking ordering physicians to anticipate, on a patient-by-patient basis, each result that could possibly result in harm to a patient if it is released immediately to a patient is too high
 - Examples that could lend themselves to limited blanket exceptions:
 - Adolescent care
 - Tests for which counseling is required
 - Unexpected results that trigger state regulatory prohibitions

Pathologists and Laboratories Have Unique Questions of ONC

- **Laboratory and pathology narrative data not yet clearly defined by ONC**
- **Definition of machine readable format**
 - **Interoperability requirements unclear in terms of pathology and laboratory data needing to be provided in structured format**
 - **Impact on electronic cancer checklists and cancer registry reporting**
- **LIS/EHR vendor platforms' ability to handle myriad state laws, formats**

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.**

Sue Chang, MD, FCAP

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City of Hope – About Us

- **NCI-designated Comprehensive Cancer Center in Southern California**
- **217 beds**
- **Multiple community infusion clinics, radiation oncology sites**
- **LIS and EHR have been on Epic since late 2017**



Prior to the Cures Act

- **OpenNotes initiative since mid-2019**
 - Certain types of outpatient notes set to release to patient portal
 - Inpatient notes not auto-released
 - Extensive discussion at medical staff meetings
- **Some test results as auto-release by late 2019**
 - Most ambulatory CP tests were automatically released on a time delay
 - Some ambulatory CP tests required manual release:
 - Drug levels, both therapeutic and drugs of abuse
 - Infectious agents
 - Pregnancy tests, betaHCG levels
 - AP results, cytogenetics and molecular results, donor testing results were blocked from release to patient portal

California Health and Safety Code § 123148(f)

- **Certain test results must not be disclosed to a patient by “Internet posting or other electronic means”:**
 - HIV antibody test, hepatitis infection, drugs of abuse, results related to “routinely processed tissues” if they reveal a malignancy
 - https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=123148.&lawCode=HSC
 - Manual release at an organizational level
- **For all other labs, the results are immediately released upon result finalization (inpatient and outpatient)**
- **For radiology reports, there is a 48h delay from report signout**
- **For now, following CA law, but it remains to be seen if this will continue**

Cures Act and Manual Blocking

- **Certain items can be blocked from automatic release in limited circumstances:**
 - Patient request to not have auto-release
 - Results need to be discussed with patient
 - Risk of harm to the patient or another person
 - The user must reasonably believe that restricting the information will *substantially* reduce the likelihood of harm
- **Use of these limitations must be patient-specific and documented**
- **A blanket restriction is not permitted**

Reason for Blocking

The image shows a screenshot of a medical software interface. At the top, there is a header for 'My Note Progress Notes' with buttons for 'Tag', 'Share w/ Patient' (highlighted with a red box), and 'Details'. Below this is a 'Cosign Required' checkbox and a rich text editor toolbar with icons for bold, italic, link, unlink, insert smarttext, undo, redo, and other functions. A modal dialog box titled 'Reason for Blocking' is open in the foreground. It contains the instruction: 'Provide the most appropriate reason why this note should be blocked from the patient.' There are three radio button options: 1. 'Sharing reveals test result not yet discussed with patient (Enter one of the following in comments: HIV, Hepatitis, test indicating drug abuse, non-blood path test showing malignancy)' - this option is highlighted with a blue box. 2. 'Patient requested note not to share due to (enter comment below)'. 3. 'Sharing this note risks the life or physical safety of the patient or another person.' Below the options is a 'Comments' text area. At the bottom of the dialog are three buttons: 'Select a reason to accept.' (with a red error icon), 'Accept', and 'Cancel'.

Manual Release of Sensitive Labs

- Physicians and APPs can manually release sensitive labs to the patient portal
- Can add a “Result Comment” that travels with the result

The screenshot displays the 'Results Release' interface for MyCityofHope. The top navigation bar includes 'Review', 'Synopsis', 'Rooming', 'Connect to Video', 'Plan', 'Treatment', 'Notes', 'MyCityofHope Results Release', and 'Wrap-Up'. Below the navigation, there are tabs for 'Mark for Release', 'All Results', 'Normal Results', and 'Set as My Default'. The main area contains a table with columns: 'Notify if Unviewed', 'Status', 'Result', 'Prevent Auto-Release', and 'Comments'. The table lists various lab results, including 'Initiative (Pregnancy), Serum', 'FTA (Tumor Marker), Blood', 'IM ANTIBODY', 'I W CONTRAST', 'COVID-19) CORONAVIRUS, (T- PCR (CITY OF HOPE)', 'V', 'V RIGHT', 'TUDIES', and 'W ASPIRATION & BIOPSY'. The 'Release' buttons for the first three rows are highlighted with red boxes, and the 'Select' buttons for the same rows are also highlighted with red boxes. A blue arrow points from the 'Select' button of the first row to the 'Select Results to Add Comments' panel on the right. This panel includes a search bar, a list of selected results, and an 'Auto-apply comments?' checkbox.

Notify if Unviewed	Status	Result	Prevent Auto-Release	Comments
<input type="checkbox"/>		Initiative (Pregnancy), Serum	<input type="checkbox"/>	<input type="checkbox"/> Select
<input type="checkbox"/>		FTA (Tumor Marker), Blood	<input type="checkbox"/>	<input type="checkbox"/> Select
<input type="checkbox"/>		IM ANTIBODY	<input type="checkbox"/>	<input type="checkbox"/> Select
		I W CONTRAST	Unrelease	<input type="checkbox"/> Select
		COVID-19) CORONAVIRUS, (T- PCR (CITY OF HOPE)	Unrelease	<input type="checkbox"/> Select
		COVID-19) CORONAVIRUS, (T- PCR (CITY OF HOPE)	Unrelease	<input type="checkbox"/> Select
		V	Unrelease	<input type="checkbox"/> Select
		V RIGHT	Unrelease	<input type="checkbox"/> Select
		TUDIES	Unrelease	<input type="checkbox"/> Select
		W ASPIRATION & BIOPSY	Unrelease	<input type="checkbox"/> Select
		W ASPIRATION & BIOPSY	Unrelease	<input type="checkbox"/> Select
		W ASPIRATION & BIOPSY	Unrelease	<input type="checkbox"/> Select
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		W ASPIRATION & BIOPSY	Unrelease	<input type="checkbox"/> Select
		W ASPIRATION & BIOPSY	Unrelease	<input type="checkbox"/> Select
		W ASPIRATION & BIOPSY	Unrelease	<input type="checkbox"/> Select

Points of Interest

- **What are your state laws?**
- **What is your patient population?**
 - Focused patient population at City of Hope, a cancer hospital
 - Primary screening of healthy patients
- **Hinges on the technical capabilities**
 - Laboratory Information System (LIS) and its interface with the EHR
 - Patient portal
- **Key Partnerships**
 - Radiology colleagues
 - CMIO, CMO, and IT group
- **Proofread your reports**
 - Impress upon your colleagues the likelihood that the patient will read their report before the oncologist

Resources

- **Cures Act Information Page**
 - Information: <https://www.cap.org/member-resources/cures-act-information>

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