21ˢᵗ Century Cures Act
Frequently Asked Questions

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General Questions About the Act

What is the 21ˢᵗ Century Cures Act?

The 21st Century Cures Act is a federal law designed to help patients quickly and easily access their electronic health information to make informed decisions about their care. The Cures Act requires healthcare organizations, like ours, to have the capability to release electronic health information, such as clinical notes and test results, to patients as soon as the information is finalized. The Act includes a provision requiring that patients be able to electronically access all of their electronic health information (EHI), structured and/or unstructured, at no cost, and outlines penalties for non-compliance or "Information Blocking".

How will the 21ˢᵗ Century Cures Act affect the organization?

Beginning Monday, December 11, 2023, additional clinical notes will be released to patients via MyChart for compliance with the 21st Century Cures Act. This is an expansion of previous 'Open Notes' initiative under the 21st Century Cures Act from 2020.

We will be required to make electronic modifications within the medical record to ensure that applicable, finalized medical information is readily available and released in a timely manner, without delay. A multidisciplinary workgroup was established between Yale New Haven Health and Yale University to implement these required changes. Examples of required regulatory changes include:

- Ensuring finalized clinical information, including notes, are released to a patient's MyChart account for viewing without delay.
- Implementing a mechanism by which clinicians and staff can block notes from flowing to the patient's MyChart account if an exception applies.
- Ensuring there is a mechanism for patients to request a download of their unstructured data for use in an external application.

Please keep in mind that while this information will now be more readily accessible to the patient via MyChart, this information has always been released by Health Information Management upon patient request.

How will the Act affect me in my role?

This Act is about transparency and patient access to information. It will primarily affect you in your role in the following ways:

1. **Expansion of Access to Notes via MyChart:** Yale New Haven Health and Yale University began sharing test results and some clinical notes under the initial Cures Act requirements in October 2020. These changes have been well received by patients due to the ease of access to their clinical information. As of December 11, 2023, we will have fully implemented the requirement and additional notes will be readily viewable to patients via MyChart.

   Please note: Draft notes, draft results, etc. will not be viewable and patients will not receive a MyChart notification each time a note is finalized.

2. **Blocking Reasons:** There are exceptions whereby a note may be blocked from being shared to MyChart. For example: to protect the privacy of another individual mentioned in the note, patient requests note not to be shared, research blinding, or to prevent substantive harm to the patient or another individual due to the content of the note.

Questions About Applicability and Scope

What information does this Act apply to?

The Act applies to Electronic Health Information (EHI) to the extent that it would be included in a designated record set (DRS), as defined by HIPAA. HIPAA defines a DRS as medical records, billing records, payment and claims records, health plan enrollment records, case management records, as well as other records used, in whole or in part, by or for a healthcare provider to make decisions about individuals.

If medical information meets the definition above, it must be shared with the patient, unless a valid exception exists.

What information will be shared with patients?

Almost everything in the electronic medical record, such as clinical notes, test results and medications, will automatically be shared with the patient through MyChart. Much of this information is already shared with patients. The difference is that patients may see some results before their provider or care team has the chance to review them. Patients also may see additional details about their visit. It is important to continue to document efficiently and objectively within the record to prevent misinterpretation or confusion.

When are these changes being implemented?

Beginning Monday, December 11, 2023, additional clinical notes will be released to patients via MyChart for compliance with the 21st Century Cures Act.

How was it decided what notes would be released?

A multidisciplinary group from Yale New Haven Health and Yale University reviewed all inpatient and ambulatory note types to understand if the routine content of the note would meet the definition of "EHI" under the Cures Act. If the note met the definition of EHI, it was set to "Share by Default" to a patient's MyChart upon final signature. Certain notes which are utilized for administrative purposes only or which did not meet the definition of EHI, were changed to "Do Not Share by Default".

Are nursing, pharmacy, or other professions' clinical notes included in the definition of "Electronic Health Information"?

Yes. Electronic health information (EHI), as defined in 45 CFR 171.102, does not specifically include or exclude notes or other clinical observations based on the type or specialty of the professional who authors them.
https://www.healthit.gov/faqs

Questions About Information Blocking

What is Information Blocking?

Information blocking is a practice that is likely to interfere with the access, exchange, or use of Electronic Health Information (EHI), except as required by law or specified in an information blocking exception. The Cures Act applied the law to healthcare providers, health IT developers of certified health IT, and health information exchanges (HIEs)/health information networks (HINs).

What are the approved reasons for restricting a note from MyChart?

1. Per patient request.
2. To prevent substantive harm to a patient or another person.
3. To protect the privacy of another individual referenced in the note as required under state or federal law.
4. For research blinding.

Will there be monitoring of restricted or blocked notes and reason codes selected?

Yes, the Yale New Haven Health Office of Privacy and Corporate Compliance (OPCC) and the Yale University Privacy Office will be monitoring restricted/blocked notes and the reason codes selected to ensure appropriate use. There are regulatory penalties if the Office of Inspector General (OIG) receives a complaint and determines that an individual or entity has committed information blocking; they may be subject up to a $1 million penalty per violation.
https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/

How do I restrict a note from being released when drafting a note in Epic?

The note will default to share with the patient. If you want to restrict the note from being released to MyChart, at the top right of the note click the 'Share w/ Patient' blue button.

My Note

Tag | Share w/ Patient | Details ⌃

Type: Plan of Care 🔍 Service: 🔍 Date of Service: 9/19/2023 📅 08:36 AM 🕐

☐ Cosign Required

Summary: [_____]

☆ | B ⊕ ᵃᵇᶜ �) ⁇ ✚ | Insert SmartText 🔳 ⇦ ⇨ ➡ ⟳ 🎤 🖼 ➡

[_____]

⏳Pend | 🗨 Share | ✔ Sign | ✖ Cancel

A pop-up will display. Select the appropriate reason for blocking and click 'Accept'.

Reason for Blocking   ✕

This note is not being shared with the patient in MyChart for the following reason:

◯ per patient request

◯ to prevent substantive harm to patient or another person

◯ to protect privacy of another individual referenced in the note as required under state or federal law

◯ for research blinding

Comments

[_____]

❗ Select a reason to accept.   ✔ Accept   ✖ Cancel

The 'Share w/ Patient' button will grey out and a yellow banner with the reason for blocking will display.

Questions About Documentation Best Practices

Are there best practices for documentation?

In most cases sharing notes should not fundamentally change the way you write your notes. It is critical that we maintain the rich information base that allows us to track care over time and communicate effectively with colleagues. It is also critical that we be able to document efficiently.

However, there are many opportunities to improve the quality of our notes and positively engage patients in the process. Helpful, best practices for documenting notes, are included below.

It is helpful to remember that patients already have a right to their medical records, including notes. Sharing notes is a great way to engage patients and emphasize plans of care or behaviors that may need to be modified to improve a patient's health.

Are there helpful tips for note writing?

Do:
- Use people first language (*e.g.*, "22-year-old woman with diabetes" rather than "22-year-old diabetic woman").
- Use supportive language when describing patient decisions (*e.g.*, "Patient chooses not to have a mammogram" rather than "Patient refuses to have a mammogram").
- Keep notes as succinct as possible.
- Document facts, but not personal opinions.
- Make sure to be specific and provide complete descriptions.
- Document exact quotes, instead of trying to paraphrase.
- Use clear, concise language without embellishment.
- Be mindful when using abbreviations or symbols.
- Make sure to document at the time of occurrence.

Avoid:
- Pulling large amounts of information into notes that may be present elsewhere in the chart.
- Using statements that don't contribute clinically and may appear to blame or criticize the patient, such as "The patient arrived 20 minutes late."
- Using subjective terms such as 'appears' or 'seems'.
- Referring to how you feel or think about something.
- Being vague or imprecise (*e.g.*, "a large amount").
- Trying to paraphrase what someone else said.
- Utilizing labels when describing a patient such as "obnoxious" or "difficult".
- Utilizing shorthand abbreviations which could have multiple meanings and are on the list of prohibited abbreviations: https://ynhh.ellucid.com/documents/view/22698.
- Including personal contact information such as a Mobile Heartbeat number or personal cell phone number, if the phone number is not intended for patient use.

What should I be cautious about including in my notes moving forward?

Staff should be cautious about including personal cell phone numbers or Mobile Heartbeat numbers in their signature line of a note, if the phone number is not intended for patient use. Patients will now be able to readily see this information and could utilize it to contact the staff member directly. If you routinely provide phone numbers to patients for assistance, please ensure you include this office/business number instead.

Additionally, if you have concerns that you are including information pertaining to another individual in the note (*e.g.*, information regarding the mother of a newborn, documenting information received from another individual regarding the patient, etc.) or if you have concerns that information may cause substantive harm to the patient or to another individual if the note was released (*e.g.*, domestic violence situations), please find guidelines on restricting release of the notes under the: Support Services Guide to Shared Notes.

Are there circumstances when I should not share a note?

Un-sharing of a note should be done sparingly and only under special circumstances:
- In some limited circumstances, the content of a note may pose a risk of harm to a patient if read by a third party. In these cases, you may choose not to share a note, especially if the patient has granted MyChart proxy access, the parent has proxy access, or the patient has shared their MyChart credentials.
  Examples might include:
  o Domestic violence
  o Legal matters (*e.g.*, child custody issues)
  o Concerns about child/elder abuse or neglect.

- In some cases, information related to another individual may be documented in the note and, for the individual's privacy, the note should not be shared. Examples might include:
  o Information related to the mother's medical history is documented in a newborn child's note.
  o Information is obtained from a third party related to the patient's care and for the privacy of the individual providing the information, the note should not be shared.

- The patient has experienced a traumatic life event and requests that information not be viewable in their MyChart account.

If you are unsure whether a note should be shared, you could discuss the situation with peers or with your clinical leadership.

Questions About How These Changes Will Affect Staff

What is the team doing to assist staff in understanding these changes?

For Yale New Haven Health, a learning module called "Sharing Notes with Patients via MyChart: 21st Century Cures Act" was assigned to job-roles that document notes within the medical record and to those who use note types that were not previously shared, on November 1st. This was assigned across all Delivery Networks.

If you did not receive this assignment and believe it is applicable to you, you can search for the assignment within Infor on the Learning Management platform. Please email privacy@ynhh.org to let us know that you did not receive the assignment and we will review to ensure other individuals with the same job-role receive this important module. The note types impacted by the December 2023 expanded release do not impact Yale Medicine clinicians whose notes have been shared since 2020 and thus this training is not being assigned to Yale Medicine clinicians and staff.

Additional resources can be located within Epic Hyperspace.

How will I know if a note was released?

Within Epic on the 'Notes' tab, you can view what notes have been shared with the patient via MyChart by scrolling to the columns on the far right. You will see a column labeled "Shared" and a Yes/No indication for each note. "Yes" means it has been shared to the patient's MyChart account; "No" means it has been blocked.

You can also see if a note was shared by opening the note and reviewing the header. If a note has a pink computer icon with a heart, it means it has been shared to the patient's MyChart account.
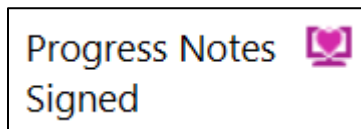
What is the difference between blocking a note and marking a note as sensitive?

Marking a note as sensitive:

- Certain users have access to mark a note as sensitive. If a note contains sensitive information that should not be shared with other organizations through Care Everywhere, click the "Sensitive" button to mark the note as sensitive. Marking a note as sensitive prevents the note from being shared via Epic Care Everywhere. A sensitive note will still be shared with the patient via MyChart.
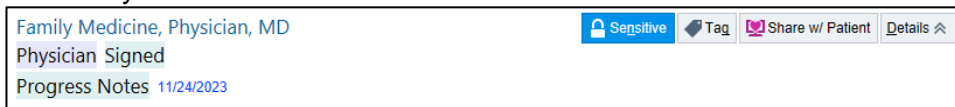
Blocking a note:

- To stop a note from being shared with a patient via MyChart, you must block the note. If a note meets any of the blocking note reasons, a user can block the note by clicking the "Share w/ Patient" button. Blocking a note will prevent the note from flowing to a patient's MyChart account.
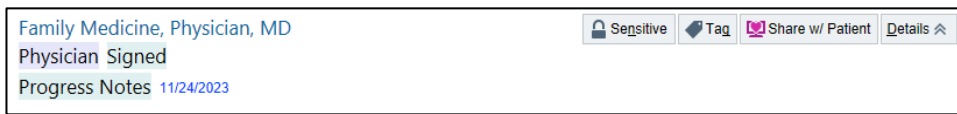
What if notes in our department were not shared with the patient via MyChart prior to December 11, 2023, will they now become shared?

No. It is important to note that this is not retroactive. If notes in your department or area were not previously shared with patients via MyChart, they will not be retroactively shared. These changes only apply to notes finalized on December 11, 2023 and after.

Will non-final clinical information, such as draft clinical notes or incomplete test results that are pending confirmation, be released to MyChart?

No, only information which is finalized and signed by all required signatories will be released to MyChart.

Will flowsheets be released to MyChart?

No, flowsheets will not be released to MyChart at this time due to the technical limitations of displaying this information in MyChart. However, if you pull flowsheet content into a note, the flowsheet will be made visible in the note itself.

What if the "Share w/ Patient" button has a yellow warning symbol ⚠️?

The yellow warning symbol ⚠️ appears when there are settings in place that prevent the note from being released to MyChart. If you see this symbol, at this time the note will not be shared to the patient's MyChart, however these notes will still be released through Health Information Management if the patient requests these notes.
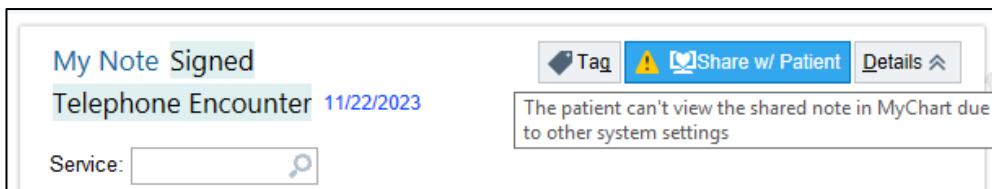
Will Plan of Care notes be released?

Yes, a Plan of Care note documents medical information about a patient and is utilized to make medical decisions about the patient, therefore they will be released to the patient via MyChart.

Will student notes be released?

Student Note Types, regardless of the note being co-signed, will not be released to MyChart. If a student documents in a generic note type, such as a Progress Note, and requests a co-signature, the note will need to be co-signed to be released to MyChart.

Please see our Epic Make Me the Author Workflow guidance document.

If I typically include my Mobile Heartbeat phone number in my note, will this be disclosed?

Yes, if documented within the note, it will be viewable by the patient and/or their MyChart proxies.

If I decide to exclude my Mobile Heartbeat phone number from the note, how can colleagues reach me?

If you do not include your Mobile Heartbeat number in your note, your colleagues can search for your name in Smart Web. Smart Web can be accessed directly within Epic in the upper banner, on the right-hand side. Please ensure your contact information is up to date in Smart Web.

Will patients receive a MyChart notification when I sign a note?

No, patients will not receive MyChart notifications when notes are released.

Can patients still obtain their notes if they request their medical records from Health Information Management?

Yes, this information has always been available to the patient if requested from Health Information Management.

Are there penalties associated with non-compliance?

Yes, on June 27, 2023, the Office of Inspector General (OIG) posted its final rule implementing information blocking penalties. The final rule establishes the statutory penalties created by the 21st Century Cures Act. If the OIG determines that an individual or entity has committed information blocking, they may be subject up to a $1 million penalty per violation.

Enforcement of the information blocking penalties began on September 1, 2023. The OIG will not impose a penalty on information blocking conduct occurring before September 1, 2023.

What should I do if a patient disagrees with or is upset by the content of a note?

Patients have a right to request changes to their medical records under HIPAA. If a provider does not feel a change is warranted, the patient has a right to file an amendment to the record describing their views.

- If you AGREE with the patient that a change is needed, you should respond to the patient and amend the note accordingly. This kind of interaction has the potential to enhance a trusting relationship.
    - If the requested change involves patient level information that may impact other notes (*e.g.*, family history, social history), please forward the message to Health Information Management (HIM) by emailing: AmendmentRequest@YNHH.ORG.

- If you do NOT feel the requested change is justified, the message should be forwarded to HIM so that they can work with the patient to file an amendment to the record if they choose to do so.

If the patient needs immediate assistance, please contact Patient Relations and/or Patient Experience for additional support.

Who do I contact if I have questions?

If you have additional questions or concerns, please contact:

For Yale New Haven Health:
The Office of Privacy and Corporate Compliance
Phone: (203) 688-8416
Email: privacy@ynhh.org

For Yale University:
HIPAA Privacy Office
Phone: 203-432-5919
Email: HIPAA@yale.edu