

Down the Rabbit Hole:

What Nurse Informatics Professionals Need to Know
About the 21st Century Cures Act

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Agenda

- Background on Information Blocking & Regulations
- Timeline
- Impacts to Healthcare Providers & Patients
- Approach to Compliance



"Well, I can't put it any more clearly, sir, for it isn't clear to me."

Alice, Alice in Wonderland



Background – Published March 9, 2020

In Federal Register on May 1, 2020

CMS Rule

- Payer Patient Access APIs
- Provider Directory APIs
- Payer to Payer Data Exchange
- **Public Reporting & Information Blocking attestation**
- Payer privacy attestations
- **ADT notifications**

ONC Rule

- Updates to 2015 Certification Criteria
- Conditions & Maintenance of Certification Requirements
- **Information Blocking**
- Health IT for Pediatric & Practice Settings



What is Information Blocking?

- A practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider **that is likely to interfere with access, exchange, or use of electronic health information (EHI)**.
- Office of the National Coordinator (ONC) Final rule requires all patient Electronic Health Information to be made available to a patient without delay, with a few exceptions
- Penalties
 - For Health IT Developers & HIEs/HINs - civil monetary penalties up to \$1M per incident
 - Health IT Developers could be banned from certification
 - For Healthcare Providers, disincentives are still being determined – may be a proposal later this fall.



Actors in the Information Blocking Rule

Healthcare Providers

Hospitals

SNFs

Home Health

Dialysis Providers

Pharmacy

Physician

Laboratory

Health Information Exchange

Entity or individual controls, determines, or administers the connection between 2 unaffiliated individuals/entities

Hospital that provides connection to HIE for affiliated private practices

Health IT Developers

Develops health IT

Offers health IT through sublicensing or other means



Definition Review

Electronic Health Information (EHI):

- ePHI included in the Designated Record Set, as defined by a covered entity.
- The Designated Record Set (DRS) refers to a group of records maintained by or for a covered entity that may include patient medical and billing records; the enrollment, payment, claims, adjudication, and cases or medical management record systems maintained by or for a health plan; or information used in whole or in part to make care-related decisions. (HIPAA)

United States Core Data for Interoperability (USCDI): standardized set of health data classes and constituent data element.



Impacted Data Elements

USCDI Data Set

<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>

Allergies and
Intolerance

Assessment and Plan
of Treatment

Care Team Members

Clinical Notes

Health Concerns

Immunizations

Laboratory

Medications

Patient
Demographics

Problems

Procedures

Provenance

Smoking Status

Unique Device
Identifier(s) for
Implantable
Device(s)

Vital Signs



Impacted Data Elements

USCDI Data Set

<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>

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Smol

- Consultation Notes
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note (a patient's interval status during a healthcare encounter)

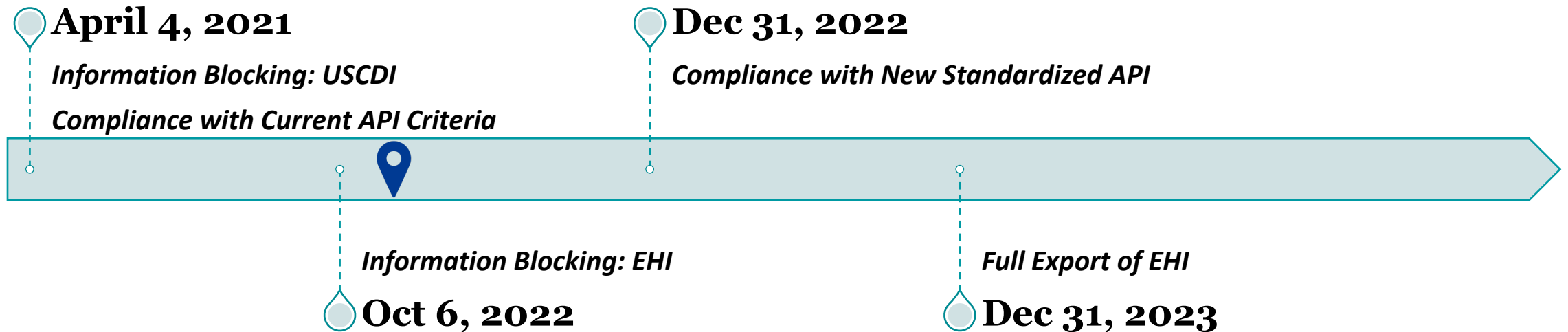


"I'm late, I'm late! For a very important date! No time to say 'hello, goodbye,' I'm late, I'm late, I'm late!"

The White Rabbit, Alice in
Wonderland



Information Blocking Compliance Timeline



“Would you tell me,
please, which way I out
to go from here?”

Alice, Alice in Wonderland



Major Changes to Sharing Patient Information at Mass General Brigham

Phase 1 (April 2021)

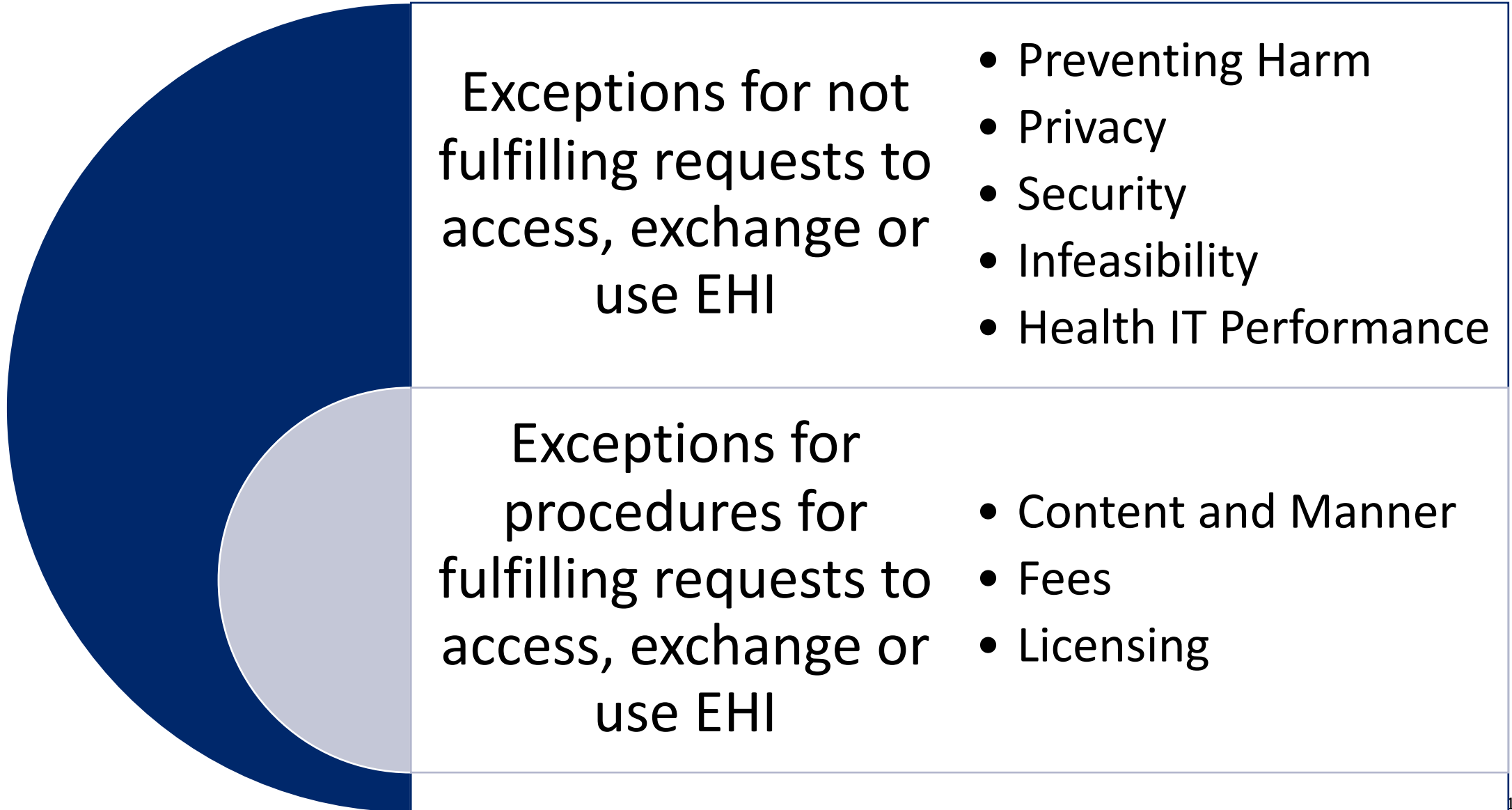
- Eliminate embargo period prior to releasing results to patients or providers.
- More note types (including inpatient) will be available in the patient portal.
- No longer possible to globally opt-out of sharing notes in portals or HIE
- Provider opting to not share an individual note must give reason

Phase 2 (October 2022)

- Historical information will be made available to patients in the patient portal.
- Additional encounter types and note types, including telephone notes, will be made available to patients in the patient portal.
- Radiology Images will be made available to patients in patient portal.



8 Exceptions to Information Blocking



Exceptions That Involve Not Fulfilling Requests To Access, Exchange, or Use Electronic Health Information

Examples that meet the exception

Preventing Harm

- A patient is denied access to their EHI because their provider has determined it would cause significant harm to the patient.

Privacy

- HIV information is not released through the physician portal without written patient authorization.

Security

- Information is blocked from a third party app after a security threat is detected.

Infeasibility

- A patient's information is unable to be retrieved from a server after a flood.
- Information cannot be segmented from the rest of the record.

Health IT Performance

- Patients are unable to access the patient portal due to an upgrade in the software.



Exceptions That Involve Procedures for Fulfilling Requests To Access, Exchange, or Use Electronic Health Information

Examples that meet the exception

Content and Manner

- A provider is unable to provide a patient's EHI in the requested format. The provider offers an acceptable alternative format to the requestor.

Fees

- A hospital charges a fee for all attorneys to access EHI via a portal.

Licensing

- IT vendor does not license interoperability elements to a requestor who is interested in learning about their technology.



Permissible Exceptions for Suppressing a Note

1. If patient requests the note is not shared.
2. If sharing the note would cause SIGNIFICANT harm to the patient's life or physical safety.
 - Emotional harm is not considered significant harm under the regulations and cannot be a reason to withhold information from patient.
 - The stress or anxiety of a “bad” result is not a reason to suppress a note.



"Nothing's impossible!"

The Doorknob, Alice in Wonderland



MGB Approach for Compliance



Formed multidisciplinary workgroup

Led by HIM, includes Legal, Compliance, Clinical Leaders & IS



Read rules and interpreted changes

Consulted Outside Counsel, professional groups



Updating policies for compliance

New Information Blocking Policy, enhanced existing policies



Design and build Epic functionality

Made changes for clinicians & patients



Creating provider education & communication

Ongoing work!



MGB Options to Mitigate

- ✓ Review with General Counsel & Outside Counsel to confirm information cannot be delayed categorically without an individualized determination this would cause significant harm to a patient
- ✓ Determined design changes that would alert providers of the consequences of blocking notes from the patient portal.
- ✓ Consider not sending email result notifications to patients
- ✓ Create a patient-friendly notification in Patient portal to inform patients that they may see their results before their provider has reviewed them
- ✓ Create an information blocking toolkit for practices and providers
 - ✓ FAQs for providers



Regulatory Language (Preventing Harm Exception)

- Only under individual circumstances as determined by the patient's licensed healthcare provider can information be withheld from the patient. *From the Regulation:*
 - “While we recognize the importance of effective clinician-patient relationships and patient communications, **we are not persuaded that routinely time-delaying the availability of broad classes of EHI should be recognized as excepted from the information blocking definition under this exception.**
 - Consistent with § 171.201(d)(3) as finalized, the harm of which a practice must reduce a risk must, where the practice interferes with the patient's access to their own EHI, be one that could justify denying the patient's right of access to PHI under § 164.524(a)(3). Currently, § 164.524(a)(3)(i) requires that for a covered entity to deny an individual access to their PHI within the designated record set, the disclosure of that PHI must be reasonably likely to endanger the life or physical safety of the patient or another person.
 - No commenter cited evidence that routinely delaying EHI availability to patients in the interest of fostering clinician-patient relationships substantially reduces danger to life or physical safety of patients or other persons that would otherwise routinely arise from patients' choosing to access the information as soon as it is finalized.”



Changes to Consider

- When providers choose to suppress a note from the patient portal, alert will pop-up.

Federal regulation mandates note sharing unless sharing would directly put your patient's life or physical safety at risk.

- Patient Friendly Language in patient portal where patient's access radiology, lab and other results.

Test results will be available in Patient Gateway as soon as they are finalized. Your care team will need time to review your results in order to discuss them.



“My dear, here we must run as fast as we can, just to stay in place. And if you wish to go anywhere you must run twice as fast as that.”

The Queen of Hearts, Alice in Wonderland



Special Considerations

Mental Health

42 CFR Part 2
records

Non-clinicians
documenting
in the record

Interpersonal
violence,
abuse



Historical Notes

Background

- When the 21st Century Cures Act final rule was first published it was not clear whether historical information needed to be shared in Patient Gateway. Since then, the Federal government has provided clarity.

From Federal Government

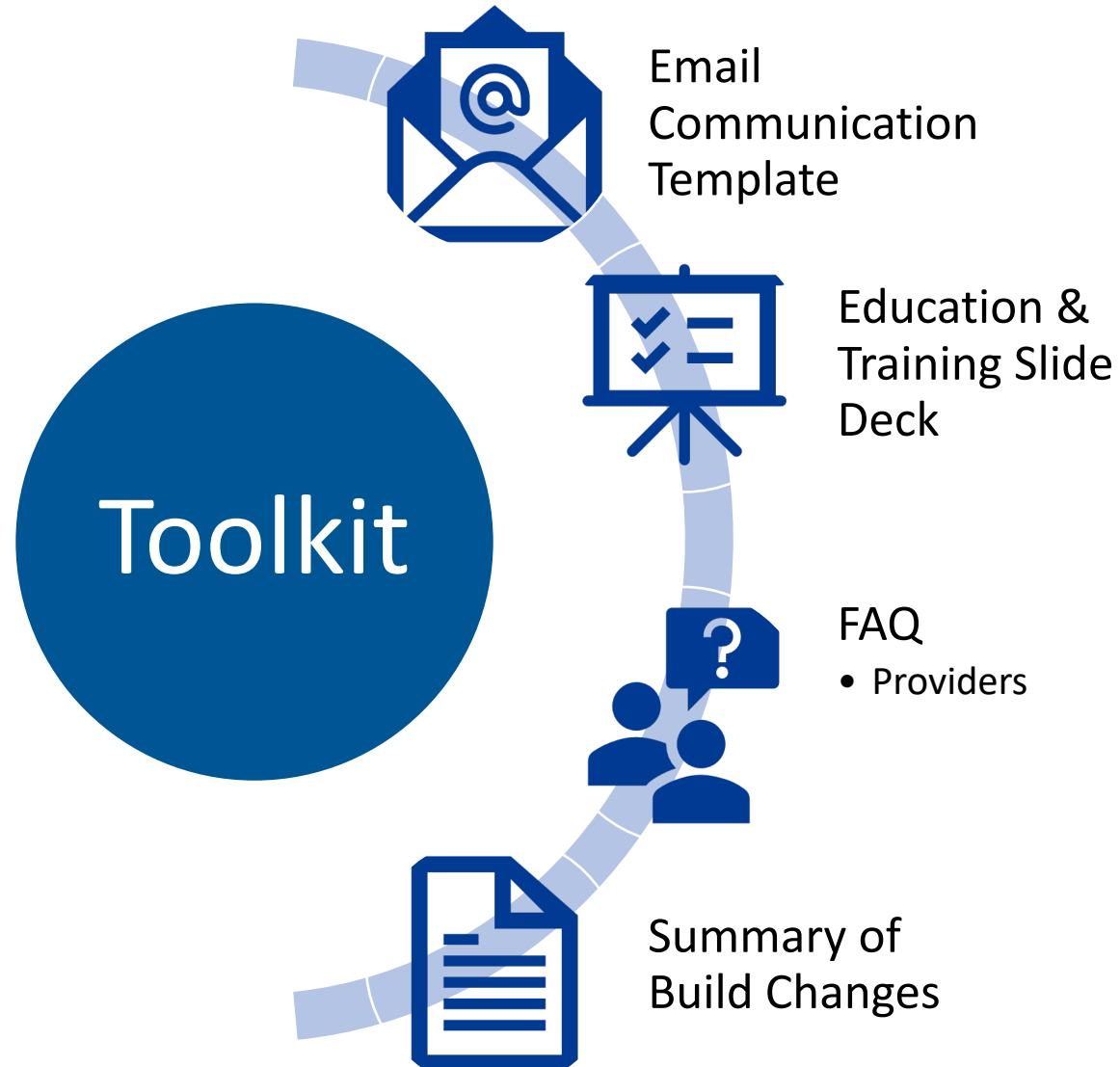
- **“Question:** Is electronic health information (EHI) that is covered by the information blocking regulations limited by when the information was generated? (IB.FAQ20.1.2020NOV)
- **Answer:** No, the definition of electronic health information (EHI) is not limited by when the information was generated...On and after October 6, 2022, an actor must respond to a request to access, exchange, or use EHI with EHI as defined in 45 CFR 171.102, **regardless of when the information was generated.**
- For example, an actor who has the necessary technical capability to do so is required to fulfill a request to access, exchange or use EHI that they have and could appropriately disclose in response to that request even if the EHI was generated before the ONC Cures Act Final Rule was published and even if the EHI was generated before the Cures Act was enacted by Congress.”

Impact

- Sharing historical notes with patients
- This information was made available by October 6, 2022.
- Patients will not receive notifications when this information is made available to them in Patient Gateway.



Toolkit for Communication & Education



FAQ 1: How to talk to patients about information sharing

The core of patient care is found in the patient provider relationship. There are several ways to assure your patients that you are there to support them:

- As part of the encounter, routinely share with patients that their test results/reports will now be accessible to them in the patient portal, resulting in the patient likely earning of the information prior to having a personal conversation with the provider.
- Let your patient know it may take you a few days to review the results.
- Let your patient know how you will reach out to them if there are urgent, unexpected or concerning results.
- Reassure your patients that there are processes in the lab and radiology to alert you to significant or unusual findings and you will communicate these with the patient.



FAQ 2: Do I Need to Change the Way I Document?

- No! Studies have shown that patients are not bothered or confused by medical terms they do not understand. Instead, they feel more prepared for their next visit. Some tips for improving notes are:
 - Be factual, clear and concise; stick to the facts, observations, clinical impressions and plan of care.
 - Be mindful of sensitive topics: patient can always access their records through Health Information Management
 - Be respectful when documenting interactions with patients and their families



“Begin at the beginning and go on ‘til you come to the end then stop.”

The King, Alice in Wonderland



Strategies for Compliance

- Read the regulation & stay up to date on new information from ONC
- Make a plan – start with what is easy
- Communicate, communicate, communicate
- Engage stakeholders across your organization



Communication Tips

- Identify a physician champion
- Solicit buy-in from Senior Leadership
- **Over** Communicate
- Provide presentations, meetings and written material
- Take the opportunity to improve documentation



Resources

Federal Government Resources

- ❑ CMS Fact Sheet: <https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet>
- ❑ CMS Final Rule: <https://www.cms.gov/files/document/cms-9115-f.pdf>
- ❑ ONC Final Rule: https://www.healthit.gov/sites/default/files/cures/2020-03/ONC_Cures_Act_Final_Rule_03092020.pdf
- ❑ ONC Webinars & Slides: <https://www.healthit.gov/curesrule/resources/webinars>
- ❑ ONC Information Blocking Exceptions Tip Sheet: <https://www.healthit.gov/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf>

Other Resources

- ❑ [Blocking and Tackling: What Every Health Care Provider's Legal, IT, and Compliance Teams Need to Know About Information Blocking to Make It Through the First Compliance Deadline's Goal Posts](#)
- ❑ [“Your Patient is Now Reading Your Note: Opportunities, Problems and Prospects”](#) from The American Journal of Medicine.
- ❑ [Open Notes](#)



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