21st Century Cures Act
Final Rule FAQ

On April 5, 2021, the U.S. Department of Health and Human Services (HHS) will require all healthcare practitioners, hospitals, laboratories, payers, and health-information networks to comply with the 21st Century Cures Act's Final Rule (https://www.healthit.gov/curesrule/). The NSGC Public Policy Committee created this FAQ document to help genetic counselors navigate and comply with these requirements.

What is the 21st Century Cures Act?
The 21st Century Cures Act provides funding for various programs and projects, including improving healthcare information technology (IT) to enable individuals to access their electronic health information (EHI) in a manner that is easy to understand, secure, and updated automatically. President Barack Obama signed this bill into law in 2016.

The Office of the National Coordinator (ONC) for Health Information Technology oversees the 21st Century Cures Act Final Rule requirements.

What is the Final Rule?
The 21st Century Cures Act's Final Rule gives patients direct access to their medical information to help them with medical-management decisions.

The Final Rule does not explicitly address genomic information, but gives individuals direct access to their health records to ensure:

- Transparency into the cost and outcomes of their care
- Information about competitive pricing in medical care
- Standardized methods to access EHI ("*interoperability*")
- Secure access, exchange, and use of their EHI at no cost
- The right to view their health data/EHI as soon as requested

Each electronic health record includes a standardized set of health data, known as the United States Core Data for Interoperability (USCDI). This includes patient demographics, allergies, immunizations, laboratory results, clinical notes, procedures, vital signs, and medications.

The Final Rule requires healthcare providers to immediately release finalized health data once requested as long as the request meets HIPAA requirements. Draft clinical notes or incomplete test results pending confirmation are not considered finalized. Health data should be securely transmitted through no-cost online healthcare IT apps accessible by computer or smartphone.

Once a request to access, exchange, or use EHI has been made, healthcare providers must timely respond to the request. In practice, this could mean a patient would be able to access EHI such as test results at the same time as their ordering clinician.

When does the Final Rule go into Effect?

The Final Rule was initially set to take effect in April of 2020 but HHS postponed this timeline twice due to the COVID-19 pandemic. It is currently set to take effect on April 5, 2021 unless HHS further postpones implementation.

Who must Follow the Final Rule?

Individuals (a.k.a. "*actors*") who must follow the Final Rule include healthcare providers, Health Information Networks/Health Information Exchanges, and Certified Health IT developers. Although health plans and other payers are not specifically identified as an actor, they also are not specifically excluded.

- *Healthcare provider:* a hospital, a healthcare clinic/facility/center, a physician, a practitioner, a pharmacist, a pharmacy, an ambulatory surgical center, a therapist, or any other category of facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary.

- *Health Information Network* or *Health Information Exchange*: an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information.

- *Health IT developer of certified health IT*: an individual or entity other than a healthcare provider that self-develops health IT for its own use or that develops and offers health information technology.

What is Information Blocking?

Information blocking is a practice that is likely to interfere with access, exchange, or use of health data and is considered an unacceptable practice with penalties for non-compliance unless certain exceptions are met. Since the Final Rule is a complaint-driven process, the HHS Office of the Inspector General will only investigate persons or entities who have had a formal complaint submitted through its office on a case-by-case basis. For practitioners and clinicians, HHS has yet to establish non-compliance fines and penalties, but actors should expect flexibility as they become comfortable with the law.

When is Information Blocking Allowed?

There are eight specific exceptions when information blocking is allowed and grants healthcare providers control over when and how they communicate results. The *preventing harm* exception is most relevant to practitioners and clinicians including genetic counselors. While the ONC does not currently define "harm," it is generally described as "reasonably likely to endanger the life or physical safety of the patient or another person."

How do I Determine if there is Risk of Harm?

Genetic counselors must balance individuals' abilities to access their genetic and genomic test results in a timely manner with the need for clinical interpretation and counseling, as well as the potential for results to cause patient harm.

A licensed healthcare professional who has a current or prior relationship with the patient should determine risk of harm. To block information, the scenario must meet *at least one* of the following criteria:

- A treating clinician determines an individualized risk of harm to a specific patient.

- It meets HIPAA requirements to limit a specific individual's right to access protected health information.
- It is consistent with the provider's written organizational policy based on a known/reasonable expert opinion that information blocking is necessary to prevent significant harm.
- It is related to data that is known/reasonably suspected to be misidentified, corrupt, or erroneous.

What does it Mean to Time Delay or Manually Release EHI?

Manual release means the ordering clinician must review EHI before the patient can review the information. Time delay means EHI is only released to the patient after a specific amount of time has passed, presumably to allow the practitioner time to review and communicate results to the patient.

Healthcare providers cannot routinely time delay releasing broad classes of EHI, but can develop an organizational policy that permits limiting access to very specific types of EHI (e.g. certain genetic testing results). Such policies should be:

- Written
- Developed with input from clinical, administrative, and technical perspectives
- Applied consistently and in a non-discriminatory manner
- Documented with the type and risk of harm, the benefit of delaying EHI release, and the conditions and activities that would take place prior to EHI release to reduce the risk of harm (e.g. individualized counseling)
- Contain documentation from experts that supports the significant risk of harm for the impacted EHI.

How might the Final Rule Affect Genetic Counselors?

Final Rule interpretation differs greatly within and among institutions/facilities and the ONC continues to update and clarify information. Genetic counselors should review institutional policies and the Final Rule implementation protocol with their employers/compliance departments. Most institutions advise their practitioners to use their best clinical judgement to interpret the Final Rule and determine when to block information.

Genetic counselors have a unique view of how genomic information affects medical care. They can educate patients, administrators, and other healthcare practitioners about the benefits and challenges of the Final Rule as it relates to genetic testing, including:

a. Providing pre-test counseling that informs patients of the possibility of results-release before discussion and interpretation with the ordering clinician

b. The need for clear, informative results in the electronic medical record

i. linking genetic test results to clinician-informed interpretation notes for improved patient understanding

ii. ensuring "scanned" results are accessible to patients and outside agencies.

b. Mechanisms to release results following practitioner review and communication and/or delayed release of results to reduce patient harm.

c. Some sensitive genomic information (e.g.: consanguinity or misattributed parentage), which may require additional privacy protections.

d. Parental consent for any minor's genetic test results.

In 2020, the American College of Medical Genetics and Genomics (ACMG) released a points-to-consider statement supporting the time delay of results after a practitioner reviews and communicates information with patients. ACMG's statement also supports genetic test reports that show both the laboratory results and clinician-informed interpretation, typically included as part of a clinical note or patient letter. According to ACMG, this is crucial for clarifying, and sometimes changing, the interpretation of results on a laboratory report.

Definitions

The Office of the National Coordinator for Health Information Technology (ONC): the principal federal entity with HHS that coordinates nationwide efforts to implement the most advanced health information technology and use electronic exchange of health information..

Electronic health information (EHI): includes medical-chart notes (inpatient and outpatient), laboratory reports, test results, imaging, and other protected medical records. EHI does not include Psychotherapy notes or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

Information blocking: a practice that is likely to interfere with accessing, exchanging, or using EHI.

Application Programming Interface (API): a software intermediary that allows two applications to interact.

Actor: a healthcare provider, health-IT developer of certified health IT, health information network, or health-information exchange.

Interoperability: standardized methods to access EHI, including health information networks that can provide patient records via various types of smartphone apps. Interoperability allows apps to interface through an API so that EHI can be transmitted between them.

Genetic exceptionalism: the belief that genetic information is qualitatively different from other types of health information and requires enhanced privacy and security protection in the electronic health record.

Resources

- ONC's Cures Act Final Rule official website: https://www.healthit.gov/curesrule/

- Health & Human Services 11/4/20 **Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency** https://www.federalregister.gov/documents/2020/11/04/2020-24376/information-blocking-and-the-onc-health-it-certification-program-extension-of-compliance-dates-and

- The interface of genomic information with the electronic health record: A points to consider statement of the American College of Medical Genetics and Genomics (ACMG). Genetics in Medicine (2020) 22:1431-1436.