21st Century Cures Act:
Potential Impacts on Vermont Providers & Hospitals

On March 9, 2020, the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS) released final rules implementing provisions of the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, aimed at enhancing interoperability in health care and providing patients with easier access to and control of their health data. According to the ONC, "the core goal of the health IT portion of the Cures Act is to provide patients with control of their health care and their medical record through smartphones and modern software apps."

The ONC Cures Act Final Rule includes interoperability requirements that apply to and require action by clinicians and hospitals, although it more heavily applies to health IT developers and health information exchanges/networks.

The CMS Interoperability and Patient Access Rule applies largely to payers, however it also includes provisions that affect providers and hospitals.

VITL prepared this material to provide guidance to providers and hospitals on the impact of the new Rules and steps they should consider taking to comply. This document does not address every requirement of the rules. We encourage all providers and hospitals to work with their IT, compliance, and legal teams to understand how the rules affect their organization and how they can best prepare to address the new requirements.

How can VITL help my organization?

VITL is available to walk providers through the key requirements of the final rule, and to help them plan and prepare their approach to compliance. This consulting is currently free of charge. Reach out to Maurine Gilbert at mgilbert@vitl.net to learn more.

What do I need to know and do?

The following pages present some areas of the new rules that providers and hospitals should prepare to address, plus additional information and resources:

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Information Blocking

Who*:* The ONC Information Blocking Rule includes guidance on the prohibition of information blocking, which applies to actors: health care providers[1], health information networks[2] or health information exchanges, and health IT developers of certified health IT (including electronic health record vendors). Actors are subject to information blocking regulations regardless of whether they use health IT that is certified under the ONC Health IT Certification Program.

What*:* In seeking to improve access to electronic health information (EHI), the Cures Act explicitly prohibits information blocking, "a practice by [an actor (see above)] that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information."

The Final Rule requires the actor to respond to any request for electronic patient data, unless use or disclosure is expressly prohibited by state or federal law including the Health Insurance Portability and Accountability Act (HIPAA). The rule specifies eight categories of exceptions to allow "common sense operational flexibility" in ensuring privacy and security of patient data and preventing harm. The exceptions are:

Information Blocking Exceptions

Involving not fulfilling requests

1. Preventing Harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT Performance

Involving procedures for fulfilling requests

6. Content and Manner
7. Fees
8. Licensing

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[1] Providers include, but are not limited to, "hospital; skilled nursing facility; nursing facility; home health entity or other long term care facility; health care clinic; community mental health center; renal dialysis facility; blood center; ambulatory surgical center; emergency medical services provider; federally qualified health center; group practice; pharmacist; pharmacy; laboratory; physician; practitioner; provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. § 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary". "Physicians" is further defined in 42 U.S.C. § 1395x to include the following: doctors of medicine or osteopathy; doctors of dental surgery or of dental medicine; doctors of podiatric medicine; doctors of optometry, but only under the "care" of a physician; and chiropractors.

[2] A health information network/exchange "means 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" between more than two unaffiliated individuals or entities or that is for treatment, payment or healthcare operations purposes defined in 45 C.F.R. § 164.501

The Health and Human Services Office of the Inspector General (OIG) maintains enforcement authority for information blocking. If OIG finds a provider to be ***knowingly*** engaging in information blocking practices, it will refer that provider(s) to the appropriate agency to apply disincentives.

Providers must have a means of sharing electronic health information beginning April 5, 2021. Health IT developers will be required to make Application Programming Interfaces (APIs) available in their products (e.g. EHRs) to support the exchange of electronic health information, with enforcement discretion beginning August 2, 2022. Providers will then be required to make these APIs available for data access.

Through October 5, 2022, the electronic health information that must be made accessible is limited to the data elements included in the United States Core Data for Interoperability (USCDI), a standardized set of data classes and elements, defined as electronic health information (EHI). Beginning October 6, 2022, the definition changes to include all electronic protected health information (ePHI).

When*:* While this prohibition took effect November 1, 2020, due to the pandemic, it will not be enforced until April 5, 2021.

- ***How to prepare:*** Consider developing a multi-disciplinary team to address interoperability and information blocking. Representation should include legal, clinical, compliance, and IT. The team should be responsible for understanding the rules, identifying how they impact your organization, developing plans to address the requirements, ensuring implementation of the plan, and monitoring ongoing compliance with the rules. The team may organize its activities using the following checklist:

Information Blocking Preparation Checklist

Review Existing Policies and Agreements

- ☐ Designate an individual to oversee compliance with the information blocking rules.
- ☐ Actors that create, access, or exchange electronic health information as part of their business model must develop transparent policies and data governance. Review your existing agreements, policies, and practices to ensure they are aligned to the new information blocking rules.
    - These might include the following policies and their associated procedures: HIPAA Access Policy, HIPAA Use and Disclosure Policy, HIPAA Security Policy, HIPAA Administrative Policy, and HIPAA definitions.
- ☐ Consider drafting an anti-information blocking policy to state your commitment to facilitating access and exchange of electronic health information.
- ☐ Create a compliant process for reporting and investigation of complaints.
- ☐ Review and update policy/process for record request turnaround time.
- ☐ Develop a process for decision-making regarding all requests for patient data and a process for documenting all decisions made.
- ☐ Review and update policy/process related to reasonable fees, if any, for medical records requests.
- ☐ Identify any vendors you work with that use or access electronic health information and ensure their compliance with the new regulations, possibly requiring written confirmation that they do not practice information blocking.
- ☐ Review and update contracts and agreements you have in place that restrict access, exchange, or use of EHI. Ensure they are in compliance with the Information Blocking Rule.

Review How You Make Patient Data Available

- ☐ Ensure you have a clear process for patients and other parties to request and obtain their data.
- ☐ Understand what capabilities your current EMR/EHR vendor offers and consider implementing any that you are not currently using to help make data more accessible. Explore your vendor's plans for offering new capabilities and complying with the ONC Rule, specifically making Application Programming Interfaces (APIs) available by the 2022 deadline.
    - Ensure you are on the waitlist to obtain any necessary upgrades to remain in compliance with the Rule.

Document Risks

- ☐ Regularly perform security risk assessments to document any security safeguards you maintain and their reasonableness.
- ☐ Identify potential risks or applicable exceptions and document your approach.

Train Staff and Keep Updated

- ☐ Regularly train appropriate staff on information blocking compliance and the new policies and procedures.
- ☐ Further interpretation and guidance of the rules are expected. Keep up to date as further guidance is provided and perform regular risk assessments to ensure compliance.

Public Reporting and Information Blocking

Who: Eligible providers participating in the Medicare Merit-based Incentive Payment Program (MIPS) or the Advanced Alternative Payment Model (AAPM), and eligible hospitals and critical access hospitals (CAHs) that participate in both the Medicare and Medicaid Promoting Interoperability Programs (PIP).

What: As part of their annual attestation process, providers will be required to attest that they:

- Did not knowingly and willfully take action to limit or restrict the compatibility of interoperability of certified electronic health record (EHR) technology;
- Have implemented technologies, standards, practices and policies to ensure that the EHR technology they use conforms with applicable health IT requirements and specifications; and
- Have responded in good faith and a timely manner to requests for electronic health information.

CMS will publicly report the names of providers and hospitals that may be information blocking based on how they attested to certain Promoting Interoperability Program (PIP) requirements.

When: This begins with data collected for the 2019 performance year data.

How to prepare: *A*ttestations should be included in annual data submissions for the CMS Promoting Interoperability Program. Providers should review the attestation statements ahead of time and address any barriers that might prevent them from attesting they are not information blocking.

Digital Contact Information

Who: Health care providers

What: Providers should ensure that they have digital contact information and submit that information to the National Plan and Provider Enumeration System (NPPES). CMS will publicly report the names of providers who do not list/update their digital contact information in NPPES to encourage data access.

When: CMS public reporting was to begin in "late 2020."

How to prepare: Providers should register for an account with the NPPES and regularly review and update in their record at https://npiregistry.cms.hhs.gov. Information should include digital contact information such as Direct Address and/or a FHIR API.

Admission, Discharge, and Transfer Event Notifications

Who: Hospitals, including psychiatric hospitals and critical access hospitals

What: CMS is changing the Conditions of Participation (CoPs) to require hospitals make a "reasonable effort" to send electronic event notifications of a patient's admission, discharge, and/or transfer to providers responsible for the patient's care.

- Notifiable events include inpatient admissions, registration in the emergency department, discharge or transfer from inpatient services, and discharge or transfer from the emergency department. A format for notices is not specified.
- Notification must at minimum include patient name, name of treating provider, and name of sending institution. Clinical information may be included, but is not required.
- Hospitals may honor provider requests, such as opting out of notifications.

When: Hospitals must meet this standard by May 1, 2021

H***ow to prepare:*** VITL has partnered with a third party to provide ADT notification services at a reduced cost using data that hospitals already submit to the VHIE. If you are interested in learning more, please contact Maurine Gilbert mgilbert@vitl.net

Other Things to Know

- The Cures Act sunsets the 2014 Edition of Health IT Certification Criteria and introduces a 2015 Edition. Extensions give health information technology developers until December 31, 2023 to make technology certified to 2015 Edition Health IT Certification Criteria available to customers (date was originally 12/31/2022).
- Health IT developers will be required to test their health information technology in real-world use situations beginning March 15, 2023.
- Under ONC API Conditions of Certification, health IT developers who develop certified health IT must meet specific technical standards for Application Programming Interfaces (APIs) that would allow one application to connect to another to exchange electronic health information (e.g. a patient using Apple Health to connect to their provider's EMR for their data). These must be available by May 1, 2022.

What is VITL doing to be in compliance with the rules?

Similar to what providers are required to do, VITL is updating policies and creating new policies and procedures to clarify our capabilities and document our anti-information blocking approach. The policies will outline VITL's approach to providing patient data and identify any instances when we cannot provide data and the reasons, in line with the designated exceptions.

VITL will initially leverage existing functionality to provide Electronic Health Information (EHI) in response to requests for patient data, as required by the rule. While not currently required, we are working to implement a Fast Healthcare Interoperability Resources (FHIR) API that will facilitate enhanced, standardized data sharing in the future.

Resources

The Office of the National Coordinator for Health Information Technology (ONC)

- ONC Cures Act Final Rule website
  https://www.healthit.gov/curesrule/
- Interim Final Rule
  https://www.healthit.gov/curesrule/download
- Fact Sheet for Clinicians and Hospitals
  https://www.healthit.gov/curesrule/what-it-means-for-me/clinicians
- Information Blocking FAQs
  https://www.healthit.gov/curesrule/resources/information-blocking-faqs

Centers for Medicare & Medicaid Services (CMS)

- Promoting Interoperability Programs Information Blocking Attestation Fact Sheet
  https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR_InformationBlockingFact-Sheet20171106.pdf
- Making Sure EHR Information is Shared Fact Sheet
  https://www.entnet.org/sites/default/files/uploads/PracticeManagement/Research/_files/2019_pi_information_blocking_fact_sheet_.pdf
- Provider Quality Payment Program
  https://qpp.cms.gov
- Eligible Hospital Promoting Interoperability
  https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information

College of Healthcare Information Management Executives (CHIME)
https://chimecentral.org/public-policy/interoperability/

Healthcare Information and Management Systems Society, Inc. (HIMSS)
https://www.himss.org/news/final-cms-interoperability-regulation-what-you-need-know

American Medical Association (AMA)
https://www.ama-assn.org/system/files/2020-10/onc-final-rule-ama-summary.pdf