The Office of the National Coordinator for Health Information Technology

Keynote / ONC Update

19th General Meetings of HSPC/CIIC

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Historic Context

- President Bush's goal in 2004

  "... an Electronic Health Record for every American by the year 2014. By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care."

  - State of the Union address, Jan. 20, 2004

- **Office of the National Coordinator (ONC):**
  - » Created in **2004** by executive order and **Legislatively mandated** in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of **2009**
  - » Executive Branch (HHS) Office of the Secretary of Health

The Office of the National Coordinator for Health Information Technology

ONC'S MISSION

Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

How does ONC do this?

- Provides for the certification and regulation of Health IT, which includes technology such as **Electronic Health Records (EHRs)** and **Health Information Exchanges** (HIEs).
- Certain health care payment programs require clinicians to use health IT that has been certified under the ONC Health IT Certification Program to provide specific clinical care and data exchange functions.
- Funding of Federal Health IT Grant Programs and Resources
- Stakeholder Convening
  - » Federal Advisory Committee Act

HITECH Act : Catalyst for Transformation

HITECH Act

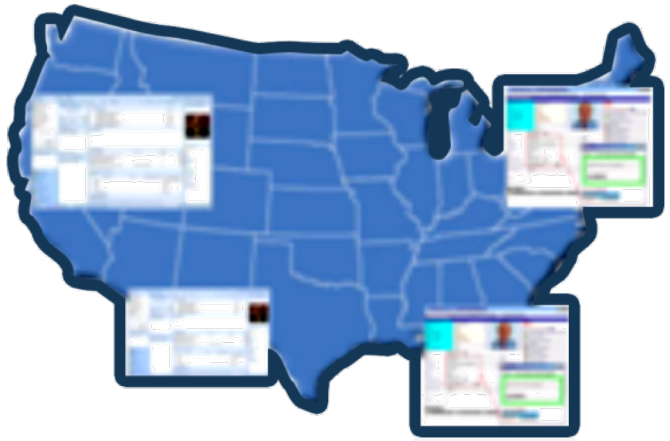
2009

EHR Incentive Program and 62 Regional Extension Centers

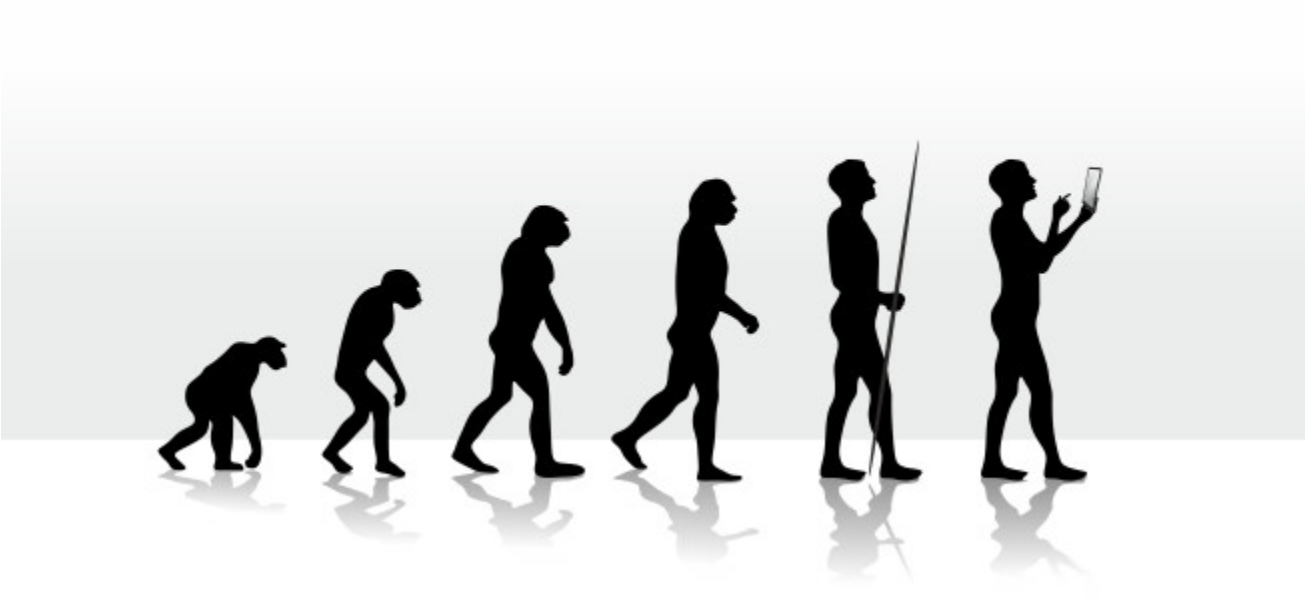
Current State

2019

Widespread adoption & use of EHRs



Next Phase of Evolution



- **Interoperability**
- **Decreasing Clinician Regulatory and Administrative Burden**

Health IT and the 21st Century Cures Act

21st Century Cures Act

A Focus on 21st Century Cures

ONC is fully focused on the two 21st Century Cures Act's priorities of increasing nationwide interoperability and improving usability/reducing clinician burden.

- Our work on interoperability includes:
  - Rulemaking to advance proposals for secure, accessible application programming interfaces (APIs).
  - Rulemaking will also identify behaviors *not* considered to be information blocking to support OIG's enforcement of Cures' information blocking provisions.
  - Advancement of a Trusted Exchange Framework & Common Agreement to set common principles, terms, and conditions that facilitate trust between disparate health information networks.
- Our work on usability includes:
  - Working closely with the Centers for Medicare and Medicaid Services (CMS) to reduce administrative and reporting burden among clinicians.

Disclaimer

- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the NPRM as it is contained in the NPRM. ONC cannot interpret that information, nor clarify or provide any further guidance.

- ONC cannot address any comment suggestion or statement made by anyone attending the presentation or consider any such comment or suggestion in the rule writing process.

The United States Core Data for Interoperability Standard

We propose to remove the "Common Clinical Data Set" (CCDS) definition and its references from the 2015 Edition and replace it with the "United States Core Data for Interoperability" (USCDI) standard. This will increase the minimum baseline of data classes that must be commonly available for interoperable exchange.

USCDI reflects the same data classes referenced by the CCDS definition and includes the following new required data classes and data elements:

- Provenance
- Clinical Notes
- Pediatric Vital Signs
- Address & Phone Number

If adopted, health IT developers will need to update their certified health IT to support the USCDI for all certification criteria affected by this change.

USCDI Standard Annual Update Schedule

ONC intends to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.

https://www.healthit.gov/NPRM

The Office of the National Coordinator for Health Information Technology

US Core Data for Interoperability Proposed Version 1

The USCDI Version 1 (USCDI v1) is proposed as a standard (§ 170.213). It reflects the same data classes referenced by the CCDS definition and includes new required data classes and data elements, noted below.

If adopted, health IT developers will need to update their certified health IT to support the USCDI for all certification criteria affected by this change.

USCDI v1

Assessment and Plan of Treatment

Care Team Members

Clinical Notes *NEW
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns

Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications
- Medication Allergies

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (including middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Address *NEW
- Phone Number *NEW

Problems

Procedures

Provenance *NEW
- Author
- Author Time Stamp
- Author Organization

Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory rate
- Body Temperature
- Pulse oximetry
- Inhaled oxygen concentration
- Pediatric Vital Signs *NEW
  - BMI percentile per age and sex for youth 2-20
  - Weight for age per length and sex
  - Occipital-frontal circumference for children < 3 years old

https://www.healthit.gov/isa/us-core-data-interoperability-uscdi

Application Programming Interface (API) Criterion

- We propose to adopt a new API criterion in § 170.315(g)(10), which would replace the "application access – data category request" certification criterion (§ 170.315(g)(8)) and become part of the 2015 Edition Base EHR definition. This new certification criterion would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications.
  - » https://www.hl7.org/fhir/overview.html

HL7® FHIR®

- Supports two types of API-enabled services:
  - » Services for which a **single patient's data** is the focus
  - » Services for which **multiple patients' data** are the focus

https://www.healthit.gov/NPRM

Application Programming Interfaces - § 170.404

API TECHNOLOGY ROLES

API Technology Supplier
Health IT developer that creates API technology presented for certification in the ONC Health IT Certification Program

API Data Provider
Health care organization that deploys the API technology

API User
Persons and entities that use or create software applications that interact with API technology

ONC has designed API Conditions of Certification that will complement the technical capabilities described in our other proposals, while addressing the broader technology and business landscape in which these API capabilities will be deployed and used.

Note: The API Conditions of Certification only apply to API Technology Suppliers with health IT certified to any API-focused certification criteria

TRANSPARENCY

ONC has proposed that API Technology Suppliers make business and technical documentation necessary to interact with their APIs in production freely and publicly accessible.

PERMITTED FEES

ONC has proposed to adopt specific conditions that would set boundaries for the fees API Technology Suppliers would be permitted to charge and to whom those permitted fees could be charged.

PRO-COMPETITIVENESS

ONC has proposed that API Technology Suppliers would have to comply with certain requirements to promote an open and competitive marketplace.

https://www.healthit.gov/NPRM

21st Century Cures Act and Interoperability

"(9) SUPPORT FOR INTEROPERABLE NETWORKS EXCHANGE.—

"(A) IN GENERAL.—The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

"(B) ESTABLISHING A TRUSTED EXCHANGE FRAMEWORK.—

"(i) IN GENERAL.—Not later than 6 months after the date of enactment of the 21st Century Cures Act, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

What is the Trusted Exchange Framework?

The Trusted Exchange Framework is a set of common principles that are designed to facilitate trust among Health Information Networks (HINs).

Principle 1 – Standardization: Adhere to industry and federally recognized standards, policies, best practices, and procedures.

Principle 2 – Transparency: Conduct all exchange and operations openly and transparently.

Principle 3 – Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.

Principle 4 – Privacy, Security, and Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.

Principle 5 – Access: Ensure that individuals and their authorized caregivers have easy access to their EHI.

Principle 6 – Population-Level Data: Exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population.

Trusted Exchange Framework and Common Agreement

GOAL 1

Provide a single "on-ramp" to nationwide connectivity

GOAL 2

Electronic Health Information (EHI) securely follows you when and where it is needed

GOAL 3

Support nationwide scalability

21st Century Cures Act and Information Blocking (Section 4004)

- Information blocking is a practice by a health IT developer, health care provider, health information exchange, or health information network that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI)
  - » May be policies, business, technical or organizational practices.
  - » Section 4004 of the Cures Act authorizes the Secretary of Health and Human Services to identify reasonable and necessary activities that do not constitute information blocking

> "(D) CONDITIONS OF CERTIFICATION.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements under this title, that the health information technology developer or entity—
>
> "(i) does not take any action that constitutes information blocking as defined in section 3022(a);

21st Century Cures Act and Information Blocking (Section 4004)

"(b) INSPECTOR GENERAL AUTHORITY.—

"(1) IN GENERAL.—The inspector general of the Department of Health and Human Services (referred to in this section as the 'Inspector General') may investigate any claim that—

"(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

"(i) submitted a false attestation under section 3001(c)(5)(D)(vii); or

"(ii) engaged in information blocking;

"(B) a health care provider engaged in information blocking; or

"(C) a health information exchange or network engaged in information blocking.

"(2) PENALTIES.—

"(A) DEVELOPERS, NETWORKS, AND EXCHANGES.—Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed $1,000,000 per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking

21st Century Cures Act 4001 (a) Reduce Clinician Buren

TITLE IV—DELIVERY

SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

(a) IN GENERAL.—The Health Information Technology for Economic and Clinical Health Act (title XIII of division A of Public Law 111–5) is amended—

(1) by adding at the end of part 1 of subtitle A the following:

"SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

"(a) REDUCTION IN BURDENS GOAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

"(1) establish a goal with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records;

"(2) develop a strategy for meeting the goal established under paragraph (1); and

"(3) develop recommendations for meeting the goal established under paragraph (1).

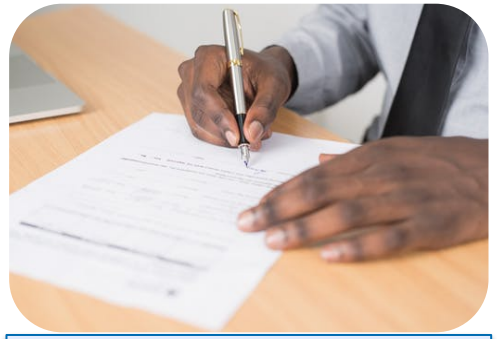
21st Century Cures Act - Section 4001. (a)
Clinician Burden Reduction Report to Congress

- **Reduction in Burdens Goal**--The Secretary of Health and Human Services shall establish a goal, strategy and recommendations with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records
- In consultation with providers of health services, health care payers, health professional societies, health information technology developers, public health entities, States, and other appropriate entities.

CMS and ONC collaborated to gain stakeholder feedback

Chief burdens reported by stakeholders

Billing-related documentation “note bloat”



Prior authorization

Quality measurement

Poor user experience with health IT and clinical workflow

Too much time outside of patient care spent on electronic records

PDMPs poorly integrated into EHRs

Strategies to Reduce Clinician Burden

Strategies to Reduce Clinician Burden

Health IT Usability and the User Experience

- Improve alignment of EHRs with clinical workflow
- Promote user interface optimization in health IT
- Promote harmonization surrounding clinical content contained in health IT
- Promote the importance of implementation decisions

Strategies to Reduce Clinician Burden

EHR Reporting

- Simplify program reporting and participation requirements.
- Reduce administrative and financial burdens associated with quality and EHR reporting programs.
- Improve electronic clinical quality measures.

Strategies to Reduce Clinician Burden

Public Health Reporting

Better integration of prescribing of controlled substances and usage of state PDMP with EHR workflow.

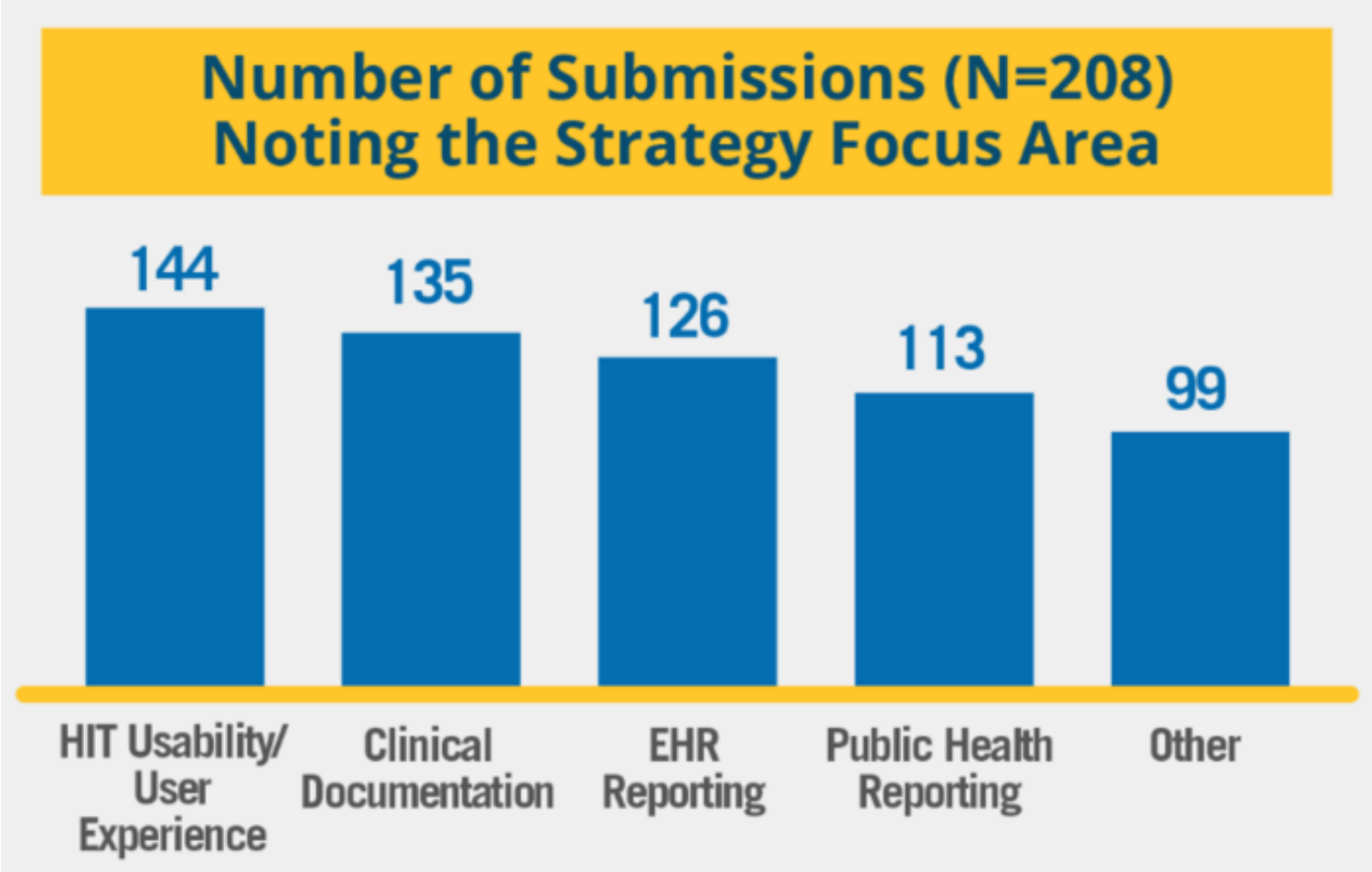
Harmonize and simplify federal and state public health reporting requirements.

Strategies to Reduce Clinician Burden

Clinical Documentation

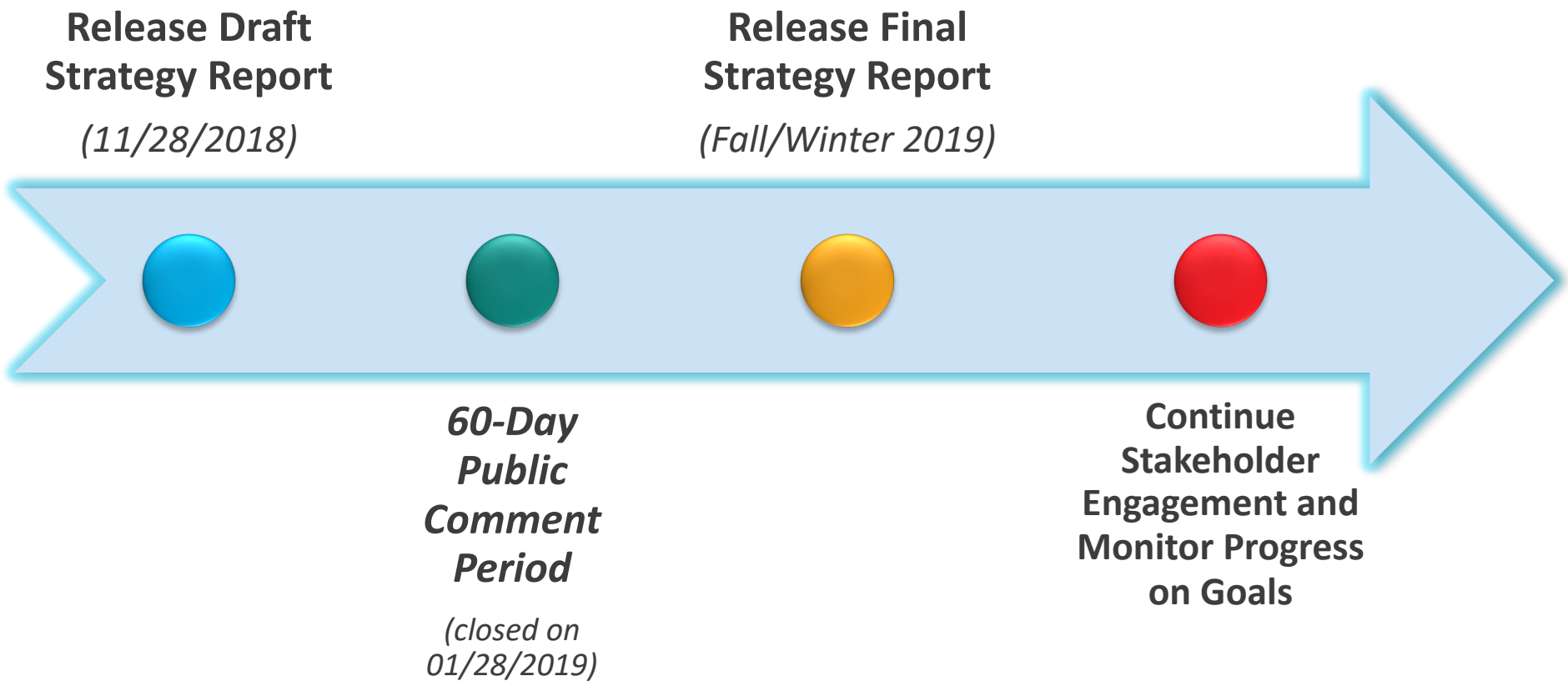
- Reduce regulatory burden around documentation requirements for patient visits.
- Clinician partnership - documentation best practices.
- Reduce documentation burden tied to prior authorization.

Public Comments on Draft Strategy



https://www.healthit.gov/burdencomments

Anticipated Timeline for Clinical Burden Reduction Strategy



Health IT Playbook

Goal: Help to resolve key issues and challenges clinicians are experiencing as it relates to health IT optimization and workflow

www.healthit.gov/playbook

Let’s Continue Building upon Progress Together

Thank you!!

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Additional Requests for Information: Exchange with Registries

- Section 4005 (a) and (b) of the Cures Act focuses on interoperability and bidirectional exchange between EHRs and registries, including clinician-led clinical data registries.

ONC is approaching these provisions from several angles to address the technical capability of EHRs to exchange data with registries in accordance with applicable recognized standards.

  - » We include an RFI in the proposed rule on how a standards-based API might support improved information exchange between a health care provider and a registry to support public health reporting, quality reporting, and care quality improvement. Public input on this RFI may be considered for future HHS rulemaking to support the bidirectional exchange of clinical data between health care providers and registries for a wide range of use cases.

Information Blocking

OVERVIEW

- Section 4004 of the Cures Act authorizes the Secretary to identify reasonable and necessary activities that do not constitute information blocking.

- In consultation with stakeholders, we have identified seven categories of practices that would be reasonable and necessary, provided certain conditions are met.

"Actors" regulated by the information blocking provision:

- Health Care Providers
- Health IT Develop ers of Certified Health IT
- Health Information Exchanges
- Health Information Networks

- The seven categories of reasonable and necessary practices, and their corresponding conditions, are defined through the exceptions proposed at 45 CFR 171.201–207.

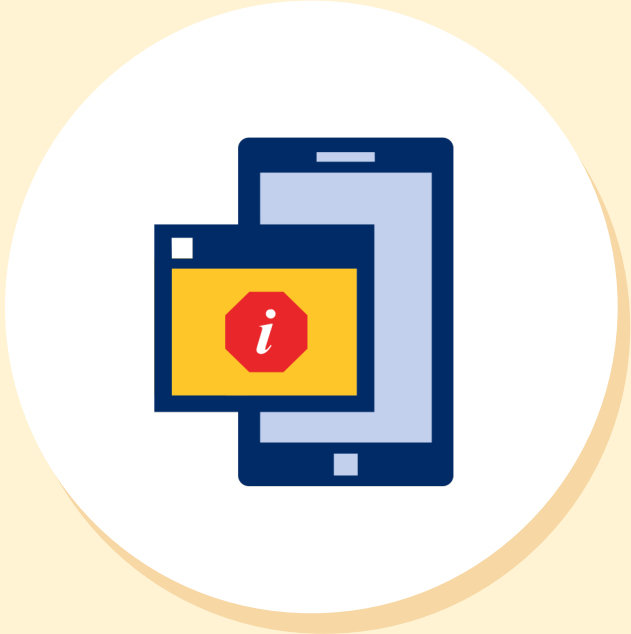
- If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy one or more exception, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.

https://www.healthit.gov/NPRM

Key Concepts

What is information blocking?

A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.



Key Concepts

Electronic Health Information (EHI)

- We propose to define EHI to mean electronic protected health information (as defined in HIPAA), and any other information that:
  - is transmitted by or maintained in electronic media (as defined in 45 CFR 160.103);
  - identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual;
  - relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
- Not limited to information that is created or received by a health care provider.
- Does not include health information that is de-identified consistent with the requirements of 45 CFR 164.514(b).

Information Blocking Exceptions

§ 171.201 Exception | Preventing Harm

- An actor may engage in practices that are reasonable and necessary to prevent physical harm to a patient or another person.
- The actor must have a reasonable belief that the practice will directly and substantially reduce the likelihood of physical harm to a patient or another person.
- The practice must implement an organizational policy that meets certain requirements or must be based on an individualized assessment of the risk in each case.

This proposed exception acknowledges that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of electronic health information (EHI).

§ 171.202 Exception | Promoting the Privacy of Electronic Health Information

- An actor may engage in practices that protect the privacy of EHI.
- An actor must satisfy at least one of four discrete sub-exceptions that address scenarios that recognize existing privacy laws and privacy-protective practices: (1) practices that satisfy preconditions prescribed by privacy laws; (2) certain practices not regulated by HIPAA but which implement documented and transparent privacy policies; (3) denial of access practices that are specifically permitted under HIPAA; (4) practices that give effect to an individual's privacy preferences.
- The information blocking provision will not require that actors provide access, exchange, or use of EHI in a manner that is not permitted under the HIPAA Privacy Rule.
- General conditions apply to ensure that practices are tailored to the specific privacy risk or interest being addressed and implemented in a consistent and non-discriminatory manner.

This proposed exception would advance the goal of preventing information blocking for improper or self-interested purposes while maintaining and upholding the privacy rights that patients now have.

Information Blocking Exceptions

§ 171.203 Exception | Promoting the Security of Electronic Health Information

- An actor may implement measures to promote the security of EHI.
- The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI.
- The practice must be tailored to specific security risks and must be implemented in a consistent and non-discriminatory manner.
- The practice must implement an organizational security policy that meets certain requirements or must be based on an individualized determination regarding the risk and response in each case.

This proposed exception would protect actors who mitigate security risks and implement appropriate safeguards to secure the EHI they control.

§ 171.204 Exception | Recovering Costs Reasonably Incurred

- An actor may recover costs that it reasonably incurs, in providing access, exchange, or use of EHI.
- Fees must be: (1) charged on the basis of objective and verifiable criteria uniformly applied to all similarly situated persons and requests; (2) related to the costs of providing access, exchange, or use; and (3) reasonably allocated among all customers that use the product/service.
- Fees must not be based on anti-competitive or other impermissible criteria.
- Certain costs would be specifically excluded from coverage under this exception, such as costs that are speculative or subjective or costs associated with electronic access by an individual to their EHI.

This proposed exception acknowledges that actors should be able to recover costs that they reasonably incur to develop technologies and provide services that enhance interoperability and promote innovation, competition, and consumer welfare.

Information Blocking Exceptions

§ 171.205 Exception | Responding to Requests that are Infeasible

- An actor may decline to provide access, exchange, or use of EHI in a manner that is infeasible.
- Complying with the request must impose a substantial burden on the actor that is unreasonable under the circumstances (taking into account the cost to the actor,
- The actor must timely respond to infeasible requests and work with requestors to provide a reasonable alternative means of accessing the EHI.

This proposed exception acknowledges that there may be legitimate practical challenges beyond an actor's control that may limit its ability to comply with requests for access, exchange, or use of EHI.

§ 171.206 Exception | Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

- An actor that controls technologies or other interoperability elements that are necessary to enable access to EHI will not be information blocking so long as it licenses such elements on reasonable and non-discriminatory terms.
- The license can impose a reasonable royalty but must include appropriate rights so that the licensee can develop, market, and/or enable the use of interoperable products and services.
- The terms of the license must be based on objective and verifiable criteria that are uniformly applied and must not be based on impermissible criteria, such as whether the requestor is a potential competitor.

This proposed exception would allow actors to protect the value of their innovations and earn returns on the investments they have made to develop, maintain, and update those innovations.

Information Blocking Exceptions

- **§ 171.207 Exception** | Maintaining and Improving Health IT Performance

  - An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT.
  - An actor must ensure that the health IT is unavailable for no longer than necessary to achieve the maintenance or improvements.
  - The practice must be implemented in a consistent and non-discriminatory manner.
  - In circumstances when health IT is supplied to an individual or entity, the individual or entity (e.g., customer) must agree to the unavailability of health IT.

The proposed exception recognizes that it may be reasonable and necessary for actors to make health IT, and in turn EHI, temporarily unavailable for the benefit of the overall performance of health IT.