ONC Proposed Rule on Interoperability and Certification

Introduction

The Office of the National Coordinator for Health IT (ONC) has released a proposed rule implementing provisions of the 21st Century Cures Act (Cures) related to electronic health information blocking, interoperability and the ONC Health IT Certification Program (Cert Program). Concurrently, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule on patient access to data and interoperability.

Provisions in these rules regarding information blocking and application program interfaces (APIs) will impact interoperability and the way data is exchanged between patients, health providers, payers, technology developers, and other health care stakeholders. The proposed rules also promote patient access and price transparency. Together, these rules signal a major push by the Administration to remove all barriers it has identified as impeding patient access to data, and to greatly expand access for payers and third-party companies. Comments are due May 3rd.

ONC Proposed Rule on Electronic Health Information Blocking, Interoperability and the Cert Program

In the proposed rule, ONC (1) defines key terms, including electronic health information (EHI); (2) provides an illustrative list of activities that would be likely to interfere with access, exchange, or use of EHI; (3) codifies compliance with the information blocking provisions as a Condition of Certification; (4) introduces seven exceptions to the general prohibition on information blocking; and (5) issues a Request for Information on disincentives for health care providers.

Information Blocking: Cures defines information blocking broadly as any practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI when the entity knows it is likely to do so. Cures directs the Secretary of the U.S. Department of Health and Human Services (HHS) to identify actions that would not be considered information blocking. ONC's proposed rule identifies seven exceptions to information blocking: preventing harm; promoting the privacy of EHI; recovering costs reasonably incurred; responding to requests that are infeasible; licensing of interoperability on reasonable and non-discriminatory terms; and maintaining and improving health information technology (health IT) performance. Additionally, ONC describes "actors" regulated by the information blocking provision: health care providers; health IT developers of certified health IT; health information exchanges; and health information networks.

The HHS Office of the Inspector General (OIG) has both investigatory and enforcement authority over information blocking and may issue civil money penalties ($1,000,000 per incident) for information blocking conducted by health IT developers of certified health IT, health information networks, and health information exchanges. The OIG may also investigate health care providers for information blocking for which health care providers could be subject to disincentives. Health care provider penalties will be established in future rulemaking. ONC proposes to implement information blocking regulations on the effective date of the final rule.

API: An API is a set of software code, protocols and tools that allows unrelated software programs to communicate with one another. They act as bridges between two applications, allowing data to flow regardless of how each application was originally programmed or designed. In health care, data sets can have different technical structures and the meaning of data (i.e., data vocabularies and terminology) may not be consistent between health IT products—making interoperability between applications challenging. Because APIs are points of communications between systems, APIs can be developed to simplify interoperability to provide providers, patients, and other data more efficiently.

ONC's proposal includes a new API certification criterion; new standards and implementation specifications; and new Conditions and Maintenance of Certification Requirements, these include:

- APIs must use updated web-based standards;
- APIs must provide an application registration process to help ensure secure connections;
- API Technology Supplier must support API-enabled services for data on a single patient and multiple patients;
- API Technology Suppliers must publish the terms and conditions applicable to their API technology including fees.

ONC proposes that API Technology Suppliers must develop, test, certify and make APIs available to their customers within 24 months of the final rule's effective date. Physicians would also be required to deploy new APIs in their clinics within the same 24 month timeframe.

EHI Export: ONC acknowledges that switching EHR systems is a time consuming and expensive activity for providers and that it is difficult for patients to access their EHI. To address this, ONC proposes to require health IT developers to provide the capability to electronically export all EHI they produce and electronically manage in a computable format. ONC proposes that health IT developers must implement this capability within 24 months of the final rule's effective date.

Conditions and Maintenance of Certification: ONC identifies several Conditions of Certification with accompanying Maintenance of Certification Requirements related to: information blocking; (health IT developer) assurances about information blocking; communications; APIs; real world testing; attestations; and future EHR reporting criteria for submission.

Communications: ONC acknowledges current developer practices that limit health IT users from openly discussing or sharing their health IT usage experiences and accordingly proposes a new Condition of Certification to protect certain communications and communicators. Within six months of the rule's effective date health IT developers must alert their customers that communication blocking contact language will not be enforced.

Real World Testing: ONC proposes a new Condition of Certification that requires health IT developers to annually submit real world testing plans and retrospective test results that include interoperability criteria. ONC proposes that health IT developers must real world test their products prior to the effective date of the final rule and provide real world tested health IT to all their customers within 24 months of the final rule's effective date.

Standards Version Advancement Process: ONC is proposing new requirements to allow developers to choose among the versions of standards and implementation specifications listed in regulation or, alternatively, National Coordinator (NC)-approved newer version updates for any or all standards applicable to criteria subject to real world testing requirements.

Quality Reporting: ONC proposes to align its Cert Program's quality reporting criterion with that of CMS' Quality Program requirements.

Electronic Prescribing: ONC proposes to align its Cert Program's electronic medication prescribing (eRx) criterion with that of CMS' Part D eRx and medication history standards requirement and to facilitate prescription drug monitoring program (PDMP) support.

Data Segmentation: ONC proposes to adopt new data segmentation and data consent standards that tag information as restricted at the document, section, and entry (data element) level and subject to restrictions on the re-disclosure. ONC primary focus is on sensitive health data related to conditions and treatments.

Health IT for Pediatric Care and Practice Settings: For pediatric settings, ONC has developed 10 recommendations for the voluntary certification of health IT for pediatric care that does not include a separate Cert Program for pediatric care and practice settings.

Requests for Information:

Price Transparency and Information Blocking
HHS states its interest in subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors, and health care providers, and includes a series of questions on how best to do this.

Trusted Exchange Framework and Common Agreement (TEFCA)
Following up on ONC's draft TEFCA from last year, ONC also issued a request for information regarding a proposal for a new Condition of Certification that would require health IT developers to participate in TEFCA to assure that they do not take any actions that would constitute information blocking.

Registries
Cures focuses on interoperability and bidirectional exchange between EHRs and registries, including clinician-led clinical data registries. ONC seeks information on how health IT solutions and the proposals throughout its proposed rule can aid bidirectional exchange with registries for a wide range public health, quality reporting, and clinical quality improvement initiatives.

Patient Matching
Inaccurate patient matching can lead to inappropriate and unnecessary care; unnecessary burden on both patients and providers to correct misidentification, time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges; and poor oversite into fraud and abuse. ONC seeks to better understand the patient matching landscape and to identify areas where ONC can assist in standards and technical development, coordination, and innovation.