The Office of the National Coordinator for
Health Information Technology

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

2018 Report to Congress

Annual Update on the Adoption of a Nationwide System for the Electronic Use and Exchange of Health Information

CONTENTS

Statutory Requirement

Section 13113(a) of the American Recovery and Reinvestment Act of 2009 under Title XIII of Division A, part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, is the underlying statutory requirement for ONC's Annual Report to Congress:

(a) REPORT ON ADOPTION OF NATIONWIDE SYSTEM.—Not later than 2 years after the date of the enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report that—

1. *Describes the specific actions that have been taken by the Federal Government and private entities to facilitate the adoption of a nationwide system for the electronic use and exchange of health information;*
2. *Describes barriers to the adoption of such a nationwide system; and*
3. *Contains recommendations to achieve full implementation of such a nationwide system.*

Executive Summary

The Department of Health & Human Services (HHS) is committed to maximizing the promise of health information technology (health IT) as a critical component in our efforts to accelerate value-based transformation in health care. HHS is committed to the use of health IT to support the free flow of health information for patients, health care providers, and payers as well as to promote competition in healthcare markets. Seamless data flow will also accelerate progress on a range of national health priorities that include combatting the opioid epidemic, spurring clinical innovation, and accelerating science.

For the past decade, the Office of the National Coordinator for Health Information Technology (ONC) has been the principal federal entity charged with supporting a nationwide health IT infrastructure, which allows for the electronic access and use of health information.

Today, most hospitals and health care providers have a digital footprint. As of 2015, 96 percent of non-federal acute care hospitals and 78 percent of office-based physicians adopted certified health IT.[1] However, hurdles to progress still remain. For example, many certified health IT products lack capabilities that allow for greater innovation in how health information can be securely accessed and easily shared with appropriate members of the care team. Such innovation is more common in other industries. Also, lack of transparent expectations for data sharing and burdensome experiences for health care providers limit the return on investment for health care providers and the value patients are able to gain from using certified health IT.

Current State

The increase in adoption of health IT means most Americans receiving health care services now have their health data recorded electronically. However, this information is not always accessible across systems and by all end users—such as patients, health care providers, and payers—in the market in productive ways. For example:

- Despite the individual right to access health information about themselves established by the HIPAA Privacy Rule, patients often lack access to their own health information, which hinders their ability to manage their health and shop for medical care at lower prices;

- Health care providers often lack access to patient data at the point of care, particularly when multiple health care providers maintain different pieces of data, own different systems, or use health IT solutions purchased from different developers; and

- Payers often lack access to clinical data on groups of covered individuals to assess the value of services provided to their customers.

Fully using modern computing tools is critical to advancing health care. Patients should be able to easily and securely access their medical data through their smartphones. Currently, patients electronically access their health information through patient portals that prevent them from easily pulling from multiple sources or health care providers. Patient access to their electronic health information also requires repeated use of logins and manual data updates.

For health care providers and payers, interoperable access and exchange of health records is focused on accessing one record at a time. Payers cannot effectively represent their members if they lack

computational visibility into which health care providers offer the highest quality care at the lowest cost. Without the capability to access multiple records across a population of patients, health care providers and payers will not benefit from the value of using modern computing solutions—such as machine learning and artificial intelligence—to inform care decisions and identify trends.

In addition, payers and employer group health plans which purchase health care have little information on health outcomes. Often, health care providers and payers negotiate contracts based on the health care provider's reputation rather than on the quality of care that health care provider offers to patients. Health care providers should instead compete based on the entire scope of the quality and value of care they provide, not on how exclusively they can craft their networks. Outcome data will allow payers to apply machine learning and artificial intelligence to have better insight into the value of the care they purchase.[2]

Future State

Health IT developers are increasingly working with **hospitals** and health care **provider practices** to identify health care provider needs and offer certified health IT that includes important upgrades that support interoperability[3] and can improve user experience.[4] The benefits of these upgrades are reflected in ONC's most recent 2015 Edition of certification criteria and standards. They will begin to show as hospitals and health care provider practices upgrade their technology to the 2015 Edition over the next few years, and as patients increasingly choose and use health IT applications that suit their needs.
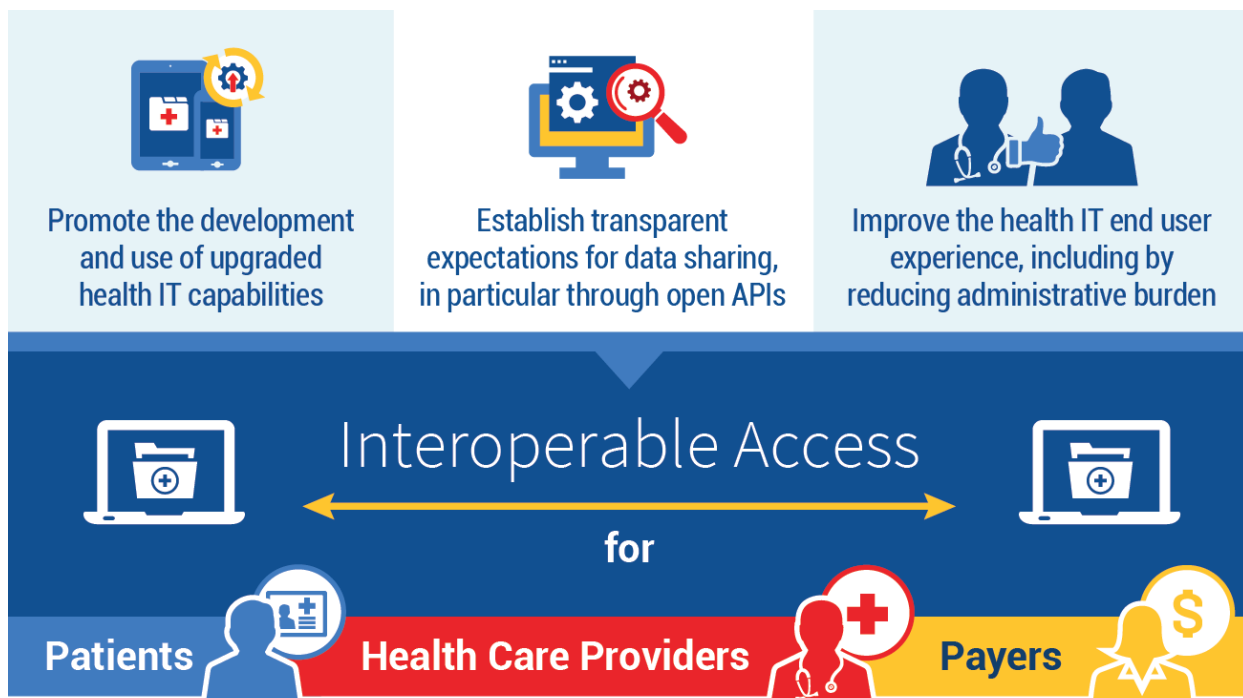
Congress provided HHS with authority to enhance innovation, scientific discovery, and expand the access and use of health information in the 21st Century Cures Act[5] (Cures Act). The Cures Act includes provisions related to:

- the development and use of upgraded health IT capabilities;

- transparent expectations for data sharing, including through open application programming interfaces (APIs); and

- improvement of the health IT end user experience, including by reducing administrative burden.

As HHS implements the provisions in the Cures Act, we look forward to continued engagement between government and industry on health IT matters and on the role health IT can play to increase competition in health care markets. One particular focus will be open APIs. Open APIs are technology that allow one software program to access the services provided by another software program and can improve access and exchange of health information. Open APIs can:

- Support patients' ability to have more access to information electronically through, for example, smartphones and mobile applications. HHS applauds the emergence of patient-facing applications that allow patients to access, aggregate, and act on their health information; and

- Allow payers to receive necessary and appropriate information on a group of members without having to access one record at a time. This can increase institutional accountability, support value-based care models, and lead to competitive medical care pricing that benefits patients.

For these reasons, interoperable access underpins HHS's efforts to pursue a health care system where data are available when and where needed. Patients, health care providers, and payers with appropriate access to health information can use modern computing solutions to generate value from the data. Improved interoperability can strengthen market competition, result in greater quality, safety, and value for the healthcare system, and enable patients, health care providers, and payers to experience the benefits of health IT.

Current Barriers

Over the past year, HHS heard from stakeholders that barriers to interoperable access to health information remain, including technical, financial, trust, and business practice barriers. These barriers impede the movement of health information to where it is needed across the care continuum. In addition, burden arising from quality reporting, documentation, administrative, and billing requirements that prescribe how health IT systems are designed also hamper the innovative usability of health IT.

HHS conducted multiple outreach efforts to engage the clinical community and health IT stakeholders to better understand these barriers, challenges, and health care provider burden. HHS is taking action to address these issues.

Current and Upcoming Actions

HHS has many efforts to help ensure that electronic health information can be shared safely and securely where appropriate to improve the health and care of all Americans. Federal agencies, states, and industry have taken steps to address technical, trust, and financial challenges to interoperable health information access, exchange, and use for patients, health care providers, and payers (including insurers). HHS aims to build on these successes through the ONC Health IT Certification Program, HHS rulemaking, health IT innovation projects, and health IT coordination.

In accordance with the Cures Act, HHS is actively leading and coordinating a number of key programs and projects. These include continued work to deter and penalize poor business practices that lead to, for

example, information blocking. HHS also aims to develop a Trusted Exchange Framework and a Common Agreement (**TEFCA**) to support enabling trusted health information exchange. Additional actions to meet statutory requirements within the Cures Act include supporting patient access to personal health information, reducing clinician burden, and engaging health and health IT stakeholders to promote market-based solutions.

Recommendations

The following are overarching recommendations for future actions HHS plans to support through its policies and that the health IT community as a whole can take to accelerate progress:

- Focus on improving interoperability and upgrading technical capabilities of health IT, so patients can securely access, aggregate, and move their health information using their smartphones (or other devices) and health care providers can easily send, receive, and analyze patient data.

- Increase transparency in data sharing practices and strengthen technical capabilities of health IT so payers can access population-level clinical data to promote economic transparency and operational efficiency to lower the cost of care and administrative costs.

- Prioritize improving health IT and reducing documentation burden, time inefficiencies, and hassle for health care providers, so they can focus on their patients rather than their computers.

Introduction

This annual report to Congress provides an overview of progress on the nationwide health IT infrastructure for the electronic access and on the use of health information to improve the health and care of all Americans and their communities. This report reflects progress on the implementations of the *Federal Health IT Strategic Plan 2015 – 2020* and the *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*. It covers the timeframe since publication of the 2016 annual report to Congress in November 2016 through October 2018.

As of 2015, 96 percent of non-federal acute care hospitals and 78 percent of office-based physicians adopted certified health IT.[6] As a result, most Americans who receive care now have their health data recorded electronically. However, this information is inaccessible across systems and appropriate end users in the market in ways that can generate value. End users also lack modern tools for accessing information that are common in other industries but are not widely available in health care.

Patients often do not have electronic *access* to their health information, which hinders their ability to manage their health and shop for medical care at lower prices. **Health care providers** often do not have electronic *access* to patient data at the point-of-care, particularly longitudinal data maintained in different health IT systems. **Payers** often do not have electronic *access* to clinical data on groups of covered individuals to assess the value of services provided to their beneficiaries.

In the Cures Act, Congress provided HHS with authority to enhance innovation and promote access and use of electronic health information. The Cures Act includes provisions that can:

- promote the development and use of upgraded health IT capabilities;
- establish transparent expectations for data sharing, including through open application programming interfaces (APIs); and
- improve the health IT end user experience, including by reducing administrative burden.

Interoperable access to health information underpins HHS's implementation of the Cures Act and is critical to its efforts to pursue a healthcare system where data is available when and where it is needed. Patients, health care providers, and payers with appropriate access to health information can use modern computing solutions (e.g., machine learning and artificial intelligence) to benefit from the data. Improved interoperability can strengthen market competition, result in greater quality, safety, and value for patients, payers, and the healthcare system generally, and enable patients, health care providers, and payers to experience the promised benefits of health IT.

HHS looks forward to working with Congress as it continues to implement provisions of the Cures Act toward the goals laid out by Congress.

Health IT Progress Update

To implement the HITECH Act, ONC established the ONC Health IT Certification Program. The ONC Certified Health IT Product List (CHPL) includes all health IT tested by an ONC-Authorized Testing Laboratory and certified by an ONC-Authorized Certification Body to meet standards, implementation specifications, and certification criteria adopted by HHS.

While adoption rates of certified health IT are high, health care providers and patients are often frustrated because the information captured by and stored in health IT systems is still not easily shared and interoperable. Research suggests that health care providers are electronically sending or receiving patient health information from outside their organization. However, health care providers have significantly lower rates of electronically finding (or querying) for patient health information from outside sources and integrating information received.[7]

The table below summarizes measures examining health care providers' interoperable health information exchange capabilities (e.g., sending, receiving, finding, integrating, and using electronic health information from outside sources) in 2015 and 2017[8, 9]:

	Percentage of office based physicians and non-federal acute care hospitals that:	Provider Group	
		Office-based physicians (2015)	Non-federal acute care hospitals (2017)
	are electronically sending or receiving (exchanging) patient health information with any health care providers outside their organization	48%	90%
	can electronically find patient health information from sources outside their health system	34%	61%
	can integrate (e.g., without manual entry) health information received electronically into their health IT	31%	53%
	had necessary patient health information electronically available from health care providers or sources outside their systems at the point of care	36%	51%

2015 Edition of Health IT Certification Criteria

HHS is committed to advancing interoperability that allows for improved querying and integrating of patient information and end user experiences. Health IT developers are increasingly making strides in this direction.[10] In 2015, through rulemaking, HHS adopted updated standards, implementation specifications and certification criteria for the ONC Health IT Certification Program, including more advanced standards and implementation specifications to support interoperability. The **2015 Edition of certification criteria (2015 Edition)** includes an API criterion and other updated technical requirements that allow for innovation to occur around APIs and interoperability-focused standards. For example, the 2015 Edition:

- Gives health care providers a greater ability to work with application developers to pull data from their health IT systems to support data analysis for purposes of participating in value-based programs and quality improvement;

- Supports more flexible and future-looking patient access to their data by enabling new types of access that go beyond patient portals, which include using APIs that support app and mobile-based solutions; and

- Gives health care providers the autonomy to export data themselves without intervention by their health IT vendor.

Health IT certified to the 2015 Edition became available to hospitals and health care provider practices in 2016. The use of 2015 Edition certified health IT is now incorporated into Centers for Medicare & Medicaid Services (CMS) payment programs. More detailed information about the capabilities of certified health IT can be found on **HealthIT.gov**.

The Cures Act

In addition to the 2015 Edition, the passage of the Cures Act has been critical to the next phase of health IT advancements. The Cures Act includes interoperability provisions aimed at building on past progress by bringing modern computing to the health care and health IT industry. It also provides HHS with the authority to address business practices of health IT developers related to interoperability. For example, the Cures Act directs HHS to:

- establish a strategy for reducing regulatory and administrative burden on health care providers relating to the use of electronic health records (EHRs);

- develop or support a trusted exchange framework for trust policies and practices and a common agreement for exchange between health information networks nationally;

- enforce the statutory provisions that penalize or deter information blocking; and

- promote patient access to health information in a manner that ensures information is available in a reasonable and convenient form for the patient, without burdening the health care provider involved. [11]

The Cures Act also directs HHS to require that the APIs developers make available do not require "special effort" on the part of the users of those APIs to access, exchange, and use health information.

Open APIs

Anyone who has ever booked a flight, reserved a hotel room, or purchased a concert ticket online has used an API. APIs have rapidly become integral to personal and business worlds. At their most basic level, APIs let one software application talk to another. [12] APIs can accelerate individuals' ability to access and transport their health information so they can shop for, coordinate, and manage their own care.[13] While patients can currently access their health information through patient portals, some find this approach frustrating. The more health care providers they have, the more portals they have to use to access their health information, the more user names and passwords they have to remember, and the more effort it is for them to access and aggregate their health information. Additionally, the patient portal offered through a health care provider may not offer the type of information that a patient needs or finds valuable. This, in turn, may prevent them from being able to shop for health coverage and care.

Research assessing individuals' electronic access and use of their health information shows that only half of individuals nationwide reported they had been offered online access to their medical record by a health care provider or insurer.[14] Of those who were offered access, half accessed their record online and only half of those accessing their records used them to communicate with a health care provider. Less than 5 percent of individuals transmitted their health record data to a service or app.[15]

Open APIs can improve individual electronic access to their health information and better support the growing market of patient-facing applications that are designed to allow individuals to access, aggregate, and act on their health information. Open APIs can also allow health care providers and payers to access appropriate information on groups of patients in batches—instead of through one record at a time. Further, enhanced APIs – those that use **Fast Healthcare Interoperability Resources (FHIR)** standards[16] – benefit patients by helping patients more easily access and share their health information on smartphones and apps.

A central principle guiding ONC's interoperability work is ensuring APIs in the health ecosystem are standardized, transparent, and pro-competitive. API solutions can allow for market-driven and patient-driven approaches to access and use of health information, rather than forcing the patients to rely on the patient portals offered by each health care provider's health IT developer.

Improved data flow through APIs can lead to better patient care and outcomes, less provider burden and wasted time, and improved healthcare and health IT markets that support not only price transparency and innovation, but also accelerate research and scientific discovery. Interoperability is critical to ensure the latest research informs clinical care; in turn, the results of interoperable clinical care should inform research and scientific inquiry.

Strategy for Reducing Regulatory and Administrative Burdens on Health Care Providers relating to the Use of Electronic Health Records

Addressing the regulatory and administrative burden associated with the use of health IT experienced by practicing clinicians requires a multipronged approach. As a component of its implementation of the Cures Act, HHS has consulted the clinical community and health IT industry stakeholders in an effort to develop strategies and recommendations that aim to reduce burden. These include focusing on EHRs and improving the clinician experience. As part of this work, HHS has also taken immediate steps to propose policies through rulemaking designed to address key burdens associated with the use of EHRs by

improving flexibility and reduce documentation requirements associated with office-based Evaluation and Management (E/M) codes used for billing within the Medicare program.

The E/M codes and associated documentation guidelines have historically allowed clinicians to use a 1-5 scale to document complexity for Medicare beneficiaries, where level 1 is the least complex visit and level 5 is the most complex visit for ambulatory outpatient encounters. The clinical community has emphasized how the E/M documentation requirements associated with this system cause many of the challenges related to the use of EHRs. In the CY 2019 Medicare Physician Fee Schedule final rule, CMS has finalized a number of documentation, coding, and payment changes to reduce administrative burden and improve payment accuracy for office/outpatient E/M visits over several years. For CYs 2019 and 2020, CMS is implementing several documentation policies to provide immediate burden reduction, while other changes to documentation, coding, and payment would be implemented in CY 2021. CMS believes these policies will allow practitioners greater flexibility to exercise clinical judgment in documentation, so they can focus on what is clinically relevant and medically necessary for the beneficiary. This rule also finalized an overhaul of EHR requirements in order to focus on promoting interoperability and included changes to help make EHR tools that support efficient care.[17]

Barriers to Progress

The potential value of health information captured in certified health IT is often limited by a lack of accessibility across systems and across different end users.

Barriers associated with health IT capabilities and data sharing

In the last 10 years, the use of certified health IT has become widespread among health care providers. However, only about half of office-based physicians are electronically exchanging health information with health care providers outside their organization.[18] Health care providers' abilities to find (or query) and integrate information from outside sources lags even farther behind. Barriers to interoperability continue to limit the access and use of electronic health information, including:

- **Technical barriers**: These limit interoperability through—for example—a lack of standards development, data quality, and patient and health care provider data matching. Addressing these technical barriers by coordinating to establish the technological foundation for standardizing electronic health information and by promoting exchange of that information can considerably remove these barriers.

- **Financial barriers**: These relate to the costs of developing, implementing, and optimizing health IT to meet frequently changing requirements of health care programs. The cost to adjust health IT to meet these requirements can impact innovation and the timeliness of technical upgrades. Specific barriers include the lack of sufficient incentives for sharing information between health care providers, the need for enhanced business models for secondary uses of data, and the current business models for health systems or health care providers that do not adequately focus on improving data quality.

- **Trust barriers**: Legal and business incentives to keep data from moving present challenges. Health information networks and their participants often treat individuals' electronic health information as an asset that can be restricted to obtain or maintain competitive advantage. Electronic collaboration with a diverse team across the continuum of care, even when the team member is

a business competitor, is critical to effective care of patients. Trust barriers inhibit this basic tenet of care.

In the Cures Act, Congress provided HHS with authority to mitigate these barriers. For example, the Cures Act penalizes and deters information blocking. The barrier created by the practice of information blocking is documented in ONC's 2015 **report to Congress**. In the 2015 report, ONC noted that the current state of technology—combined with the structure and conditions of health IT and health care markets—creates powerful incentives for some actors to pursue and exercise control over information in ways that significantly limit its availability and use.

HHS met with diverse stakeholders to hear their stories and examples of information blocking. These firsthand perspectives provided helpful background on how information blocking occurs and its real life impact on patients. HHS looks forward to continue working with stakeholders to implement the Cures Act related to these important provisions.

Barriers associated with health care providers' experience with health IT

In the Cures Act, Congress directed HHS to consult health care providers and other stakeholders to develop a goal, strategies, and recommendations to reduce the burden on health care provider associated with the use of EHRs. ONC and CMS conducted three public listening sessions attended by several hundred stakeholders across the health care spectrum to better understand the challenges associated with the use and usability of health IT. Based on stakeholder feedback, HHS aims to address burden arising from federal documentation and administrative requirements, federal reporting requirements, and health IT system design and usability issues.

- **Federal documentation and administrative requirements** (including billing requirements) contribute to health IT burden due to outdated guidelines for evaluation and management (E/M) codes that unnecessarily link payment to documentation. This linkage, over time, has created a clinical document with information that is often not relevant to the patient's care. Clinicians have expressed the need to have incentive programs aligned across HHS. They also requested commercial payers reduce the amount and type of documentation that they require of health care providers for purposes of documenting adherence to multiple programs.

- **Federal reporting requirements** in some cases add burden to health care providers by requiring them to report on quality measures that are not relevant or meaningful. Multiple reporting programs for multiple payers drive health care providers and organizations to use third party organizations such as registries and data warehouses. This often leads to increased operating costs.

- **Health IT system design and usability** barriers identified by stakeholders include the lack of alignment with real-world clinical workflows and the differences in user-interface design across developers. Stakeholders identified other barriers, such as variations in the design that make day-to-day use complicated when a health care provider uses multiple systems and the lack of developer engagement with end users of health IT regarding design needs.

Actions Taken

HHS thanks the many stakeholders that contributed to the identification of barriers to health IT advancement and shared their thoughts on interoperability and usability within the nationwide health IT infrastructure. HHS has taken and will continue to take steps, often in coordination or collaboration with other stakeholders, to address these barriers as HHS implements the health IT provisions in the Cures Act.

Action taken associated with health IT capabilities and data sharing

With the enactment of the Cures Act, Congress provided HHS with key provisions for advancing interoperability and bringing modern computing to the healthcare and health IT industry. Additionally, the administration issued the **Executive Order to Promote Healthcare Choice and Competition across the U.S.** Since then, CMS announced a series of initiatives to break down barriers that limit patients' ability to access their medical records so they can take their data with them from health care provider to health care provider.

In 2017 and 2018, leading technology companies in the private sector entered the health care space and are using–or have committed to use–FHIR-based, open standards APIs in their technical strategies.[19,20] These companies are collaborating with health IT and health care organizations to leverage FHIR standards to access, exchange, and use electronic health information. HHS wants this innovation and progress of the private sector to continue to flourish, while addressing the gaps in policies and technology that continue to inhibit patient access and interoperability.

These public and private sector efforts build on existing actions taken to implement the ***Federal Health IT Strategic Plan 2015 – 2020*** and the ***Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap.*** They also provide ONC, CMS, and other federal partners with opportunities to improve the nationwide health IT infrastructure and increase electronic access to, and use of, health information to improve care delivery.

Since November 2016, some of the most significant policy and coordination actions to advance the nationwide health IT infrastructure are:

- Health IT certified to the 2015 Edition became available to hospitals and health care provider practices in 2016. ONC updated the ONC Health IT Certification Program to implement the **2015 Edition** and associated testing processes—including capabilities aimed at supporting interoperability of health information. The CHPL includes all health IT products tested by an ONC-Authorized Testing Laboratory and certified by an ONC-Authorized Certification Body to meet standards, implementation specifications, and certification criteria adopted by HHS. Health IT developers are increasingly making available certified health IT to hospitals and health care provider practices that include these important upgrades.[21] The benefits of these upgrades will begin to show in the market as hospitals and health care provider practices upgrade their technology in the next few years. These updated requirements to which health IT products are now certified include:
    - A Consolidated Clinical Document Architecture (C-CDA) requirement that supports the improved display of data based on clinical relevance and helps ensure that data conform to applicable standards;

- An API criterion that gives health care providers a greater ability to work with application developers to pull data from their health IT to support data analysis purposes;

- An updated data set for interoperability; and

- A revised requirement that certified health IT be able to export data from one patient, a set of patients, or a subset of patients.

- CMS and ONC provided technical assistance to states on health IT, health information exchange, and interoperability. For example, the **CMS State Innovation Models (SIM) Initiative** advances state multi-payer health care payment and delivery system reform models, which help create the business case for interoperability.

- In 2016, the Agency for Healthcare Research and Quality (AHRQ) launched **CDS Connect,** a web-based platform for sharing interoperable clinical decision support (CDS). When well-implemented and thoughtfully integrated into clinical workflow, CDS can improve health care processes, such as improving preventive care. Currently, health care systems develop CDS largely independently from each other, yet standards are emerging that help developing and sharing CDS more efficiently across systems. CDS Connect leverages HL7 FHIR and Clinical Quality Language (CQL). CDS Connect is part of AHRQ's overall effort to advance evidence into clinical practice through CDS and to make CDS more shareable, standards-based, and publicly-available.

- In December 2016, ONC, through a Cooperative Agreement with the National Governors Association, released a comprehensive road map to support states' efforts to improve interoperability. The report, **Getting the Right Information to the Right Health Care Providers at the Right Time: A Road Map for States to Improve Health Information Flow Between Providers,** analyzes the differences in state health privacy laws, discusses the impact of market conditions and incentives upon data sharing, and provides a road map for states to improve the flow of electronic health information.

- The HHS Office for Civil Rights (OCR) continued to provide industry guidance on HIPAA privacy and security related topics such as **patient access**, **exchange of mental and behavioral health information (including opioid overdose)**, **HIV information**, **cybersecurity**, **mhealth**, and **sharing** patient health information with family, friends and caregivers. OCR also released **education for health care professionals** and **education for patients** on patients' rights to access their health information—including the national campaign **Get It, Check It, Use It**. Also, ONC released an interactive **consumer guide** on how patients can make the most of getting access to their electronic health information.

- In August 2017, ONC hosted the **Beyond Boundaries: 2017 Technical Interoperability Forum** for stakeholders involved in the implementation or development of health IT systems. The forum included over 250 leaders in health IT from government and industry in an open dialog about improving technical aspects of interoperability. It included advancing the use of APIs in healthcare. In August 2018, ONC held a follow up **forum** with 375 participants that covered specific technological impediments to interoperability. The areas identified through these forums inform ONC policy development and technological requirements, recent efforts to advance interoperability nationwide, and concrete actions in response to current interoperability barriers.

- In September 2017, the **Food and Drug Administration (FDA) issued guidance to device manufacturers** on developing smart, safe medical interactions. The guidance calls on developers to design their devices with interoperability of health information as an objective; conduct

- appropriate verification, validation, and risk management activities; and clearly specify to the user the relevant functional, performance, and interface characteristics.

- Multiple HHS efforts advanced standards identification, testing, and validation. The Sync for Science API enables individuals to connect a research app to their electronic health data facilitating data donation for the National Institutes of Health (NIH) **All of Us Research Program**. In 2018, ONC released educational guidance on **Key Privacy and Security Considerations for Healthcare Application Programming Interfaces**. **Sync for Genes** advances FHIR standards to communicate information from clinical genomic labs for universal use across medicine. The **Structured Data Capture** initiative progressed standards necessary for health IT to reuse data captured for other purposes such as clinical research, patient safety event reporting, public health reporting, and determinations of coverage.

- In 2017 and 2018, ONC funded a number of challenges for health IT developers, including (1) ONC's **Move Health Data Forward Challenge** that promoted the development of technology solutions that enable consumers to authorize the movement of their health data to destinations they choose, utilizing new standards and technologies like Health Relationship Trust and User-Managed Access; and (2) ONC's Privacy Policy Snapshot Challenge incentivized the creation of easy-to-implement, customizable versions of the **Model Privacy Notice** (MPN) that further assist consumers. The MPN is an open source resource designed to help third-party health IT application developers provide a transparent notice, analogous to a nutrition label, to consumers about what happens to their data.

- Artificial intelligence—the ability of computers to learn human-like functions or tasks—has shown great promise in health care. A December 2017 JASON report, *Artificial Intelligence for Health and Health Care*, concluded that the broad advances in artificial intelligence are significant and real.

- In December 2017, Capability Maturity Model Integration Institute announced the **Patient Demographic Data Quality (PDDQ) Framework**, developed in partnership with ONC. The framework was created to improve patient safety by helping organizations accurately and consistently match patient data internally and between organizations.

- In January 2018, ONC released the draft **Trusted Exchange Framework** and draft **US Core Data for Interoperability (USCDI) Version 1**. Once finalized, the Trusted Exchange Framework and Common Agreement will establish a set of common principles, terms, and conditions to facilitate trust between health information networks. The Common Agreement, a national exchange agreement, will be a legally binding contract that Qualified Health Information Networks (QHINs) and Health Information Networks will voluntarily sign onto and agree to abide by. The USCDI Version 1 aims to specify a common set of data classes that are required for interoperable exchange and identifies a predictable, transparent, and collaborative process for adding additional data classes over time. The newly formed **Health IT Advisory Committee (HITAC)** provided the National Coordinator with recommendations on the draft Trusted Exchange Framework and Common Agreement and on the USCDI.

- ONC engages with health care payers and federal partners as well as other health care and health IT stakeholders to address the needs of the value-based care community by accelerating the adoption of FHIR-based, open standards APIs that can supply valuable clinical information and the exchange of this information between health care providers and payers. For example:

- ONC participates in and provides technical assistance and subject matter expertise to HL7–a standards development organization–on the **Da Vinci Project**, which began in January 2018 as a private sector-led initiative focused on building and testing FHIR-based, open standards APIs and then developing and making publicly available corresponding implementation guides for health care providers and payers. Developing health IT tools to help health care providers streamline and expedite the process of obtaining prior authorization for health care services is an example of a use case of this type of private sector partnership.

- From November 2017 to October 2020, ONC is convening the **Payer + Provider (P2) FHIR Task Force**. It focuses on finding ways to foster the environment and infrastructure that would ensure wide-scale adoption and use of FHIR-based, open source solutions for payers and health care providers, including many of the standardized solutions developed by and funded through the Da Vinci Project.

- As of February 2018, more than 600,000 eligible hospitals and eligible professionals were registered participants in the Medicare and Medicaid EHR Incentive Programs.[22] The payment adjustment for eligible professionals under Medicare EHR Incentive Program will end in 2018. Starting in 2017, eligible clinicians–many of whom may have been considered eligible professionals for purposes of the Medicare EHR Incentive Programs–now report under the **Quality Payment Program (QPP)**. CMS's implementation of the QPP includes requirements for the use of certified health IT. In the FY 2019 Inpatient Prospective Payment System and the Long-Term Care Hospital Prospective Payment System final rule, CMS renamed the EHR Incentive Programs as the **Promoting Interoperability Programs** to better reflect their focus on improving interoperability and patient access to health information.

- In March 2018, the White House announced **MyHealthEData**, a government-wide initiative designed to help patients access and share their medical data securely and privately. MyHealthEData is intended to help patients gain electronic access to, and true control over, their own health records from the device or application of their choice. The MyHealthEData initiative will work to make clear that patients deserve to not only electronically receive a copy of their entire health record, but also to be able to share their data with whomever they want. Patients can use their information to actively seek out health care providers and services that meet their unique healthcare needs, have a better understanding of their overall health, prevent disease, and make more informed decisions about their care.

- Also in March 2018, CMS announced **Blue Button 2.0** as part of the MyHealthEData initiative. Blue Button 2.0 is a FHIR-based API that contains four years of Medicare data for 53 million Medicare beneficiaries. This API is a new way for Medicare beneficiaries to control their own claims data by providing it in a universal, secure digital format. Blue Button 2.0 is a health IT developer-friendly, standards-based API enabling beneficiaries to connect their claims data to the applications, services and research programs they choose.

- California successfully piloted and tested the **Patient Unified Lookup System for Emergencies (PULSE)**, an electronic system that grants first responders access to patient health records. In March 2018, the Sequoia Project adopted PULSE as a public-private collaboration and to serve as a tool to ensure cities, counties, and states are prepared for disasters. Sequoia is working to onboard additional state partners and communities to PULSE.

- ONC updated the **Interoperability Standards Advisory (ISA)** (most recently in March 2018), a catalog of standards and implementation specifications that advance the seamless and secure flow of electronic health information. The ISA is an interactive online platform that enables near real-time updates for a social network of users. The latest ISA addresses 142 distinct interoperability needs by identifying standards and implementation specifications for health IT developers to use.

- In April 2018, CMS announced a new **Data Driven Patient Care Strategy** as part of the MyHealthEData initiative. The Data Driven Patient Care Strategy is based on three critical cornerstones: putting patients first, making more data available (in a secure manner), and taking an API-based approach to exchanging data with CMS partners in a secure and private manner.

- The US Department of Defense (DoD) and the US Department of Veterans Affairs (VA) are users, developers, and purchasers of health IT that provide healthcare services in over a thousand facilities to millions of service members and veterans. In May 2018, VA **announced** signing a contract with Cerner that will modernize the VA health care IT system and help provide seamless care to veterans as they transition from military service to veteran status, and when they choose to use community care. With this contract, VA will adopt the same EHR platform as DoD. DoD completed its pilot phase of **MHS GENESIS**, an EHR designed in partnership with a commercial developer. A nationwide rollout is expected after the pilot rollout and will continue through 2022.

- The Substance Abuse and Mental Health Services Administration (SAMHSA) issued a **final rule to update 42 CFR Part 2 regarding the Confidentiality of Substance Use Disorder Patient Records** regarding electronic exchange of behavioral health information. The updated regulations help facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. In collaboration with ONC, SAMHSA in 2018 released two fact sheets on 42 CFR Part 2, titled: *Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?* and *Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data?* The first fact sheet helps clarify what a Part 2 Program is and depicts patient encounter scenarios so health care providers can determine how Part 2 applies to them. The second fact sheet describes how Part 2 applies to the electronic exchange of health care records with a Part 2 Program.

- CMS has signed off on California's Health IT for Emergency Medical Services (EMS) proposal for $40 million through September 2021. This project will facilitate emergency care and disaster response by developing bi-directional connections between local health information exchange and EMS agencies and health care providers, local hospitals, and medical professionals. It will also advance care coordination by allowing Medicaid providers to meet meaningful use requirements through improved health information exchange and advancing interoperability tools and services for EMS, community paramedics, and end-of-life decisions and disaster medical responses.[23]

- In July 2018, ONC published a report, **Electronic End-of-Life and Physician Orders for Life-Sustaining Treatment (POLST) Documentation Access through Health Information Exchange**, which shares the stories of how four states (California, New York, Oregon and West Virginia) are attempting to integrate POLST documents through health information exchange to—improve access for health care providers and patients. Progress in health IT can help facilitate access to advance care planning documents for health care providers and families to contemplate their end-of-life wishes for medical care and support.

- In August 2018, ONC published a **Request for Information (RFI)** in the Federal Register to ask the public for input on their views regarding implementation of the Cures Act EHR Reporting Program. The program is intended to reflect input from developers and voluntary input from end users of certified health IT on reporting criteria related to: security, usability, interoperability, conformance to certification testing, and others areas as appropriate.

Actions taken associated with end user experience with health IT

To implement key provisions of the Cures Act aimed at improving usability of health IT, reducing regulatory and administrative burden, and preventing information blocking, HHS engaged the clinical community and health IT industry stakeholders to better understand the root causes of burden associated with the usability and use of health IT.

To reduce regulatory and administrative burden, CMS and ONC are working with stakeholders and payers to:

- Decrease documentation requirements for patient encounters and explore best practices for documentation based on input from the clinical community;

- Address reporting burden by identify ways to simplify program requirements;

- Explore ways of harmonizing reporting requirements that rely on health IT data; and

- Identify health IT usability best practices that would improve the efficiency, experience, workflow, and satisfaction of end users.

CMS has already made strides towards simplifying its documentation and reporting burden by issuing guidance that clarifies requirements (e.g., requirements for signatures) as well as developing an API to streamline reporting under the QPP for health care providers using registries.

In addition, CMS, as part of the 2019 Medicare Physician Fee Schedule final rule, is improving payment accuracy for office/outpatient E/M visits over several years. CMS believes that these changes will allow clinicians greater flexibility to exercise clinical judgment in documentation. They would result in more efficient, effective use of electronic records in clinician's offices and improve the workflows needed to support patient-centered care instead of focusing on meeting billing document requirements.

CMS, in conjunction with ONC, HL7 and other payers, is also working on the Da Vinci Project, which aims to improve clinician workflow by standardizing prior authorization lookup services for all payers.

The implementation of the Cures Act builds on existing actions to improve experience of health care providers and patients in using health IT. To implement the *Federal Health IT Strategic Plan 2015 – 2020*, HHS made available, to health care providers digital information resources in an easy-to-navigate format to ease the burden of implementing and using health IT.

ONC maintains the **Health IT Playbook**, an online resource that gives health care providers actionable recommendations for addressing challenges in implementing health IT, including strategies, recommendations, and best practices for comparing health IT and negotiating key terms with health IT developers. In 2017, content from the ONC Safety Assurance Factors for EHR Resilience Guides was incorporated into the Health IT Playbook, including updated guidance on contingency planning (that can aid when recovering from a ransomware attack) and test results/follow-up reporting.

Recommendations

Collaboration and innovation are critical to the continued progress on the nationwide health IT infrastructure. HHS recommends continued and full support for implementation of the health IT provisions in the Cures Act.

In addition, the following are overarching recommendations for future actions for the health IT stakeholder landscape that can help accelerate progress:

- Focus on improving interoperability and upgrading technical capabilities of health IT, so patients can securely access, aggregate, and move their health information through their smartphones (or other devices) and health care providers can easily send, receive, and analyze patient data.

- Increase transparency in data sharing practices and strengthen technical capabilities of health IT so payers can access population-level clinical data to promote economic transparency and operational efficiency to lower both the cost of care and administrative costs.

- Prioritize improving health IT and reducing documentation burden, time inefficiencies, and hassle for health care providers, so they can focus on their patients rather than their computers.

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[1] https://dashboard.healthit.gov/report-to-congress/2016-report-congress-examining-hitech-era-future-health-information-technology.php#appendix

[2] https://www.healthit.gov/buzz-blog/interoperability/achieving-the-interoperability-promise-of-21st-century-cures/

[3] Section 4003 of the Cures Act provides that interoperability: (1) enables secure exchange and use of electronic health information without special effort on the part of the user; (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use; and (C) does not constitute information blocking.

[4] https://dashboard.healthit.gov/quickstats/pages/2015-edition-market-readiness-hospitals-clinicians.php#hospitals; https://dashboard.healthit.gov/quickstats/pages/2015-edition-market-readiness-hospitals-clinicians.php#clinicians

[5] https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf

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[8] ONC Analysis of the National Center for Health Statistics 2015 National Electronic Health Record survey.

[9] ONC Analysis of the American Hospital Association (AHA) Information Technology (IT) Supplement 2017 survey.

[10] https://dashboard.healthit.gov/quickstats/pages/2015-edition-market-readiness-hospitals-clinicians.php#hospitals; https://dashboard.healthit.gov/quickstats/pages/2015-edition-market-readiness-hospitals-clinicians.php#clinicians

[11] This is consistent with the HIPAA Privacy Rule, which provides that an individual has the right to receive the information electronically and in the individual's preferred form and format if the entity has the ability to readily produce it. See 45 CFR 164.524

[12] https://www.healthit.gov/playbook/certified-health-it/#section-2-3

[13] https://www.healthit.gov/playbook/pe/chapter-6/

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[16] FHIR standard is being developed by Health Level 7 (HL7) which is an ANSI accredited organization. HL7 uses a consensus-driven approach.

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