



Office of the National Coordinator  
for Health Information Technology



# 2022 Report to Congress

Update on the Access, Exchange,  
and Use of Electronic Health Information

**Prepared by:**

The United States Department of Health and Human Services (HHS)  
Office of the National Coordinator for Health Information Technology (ONC)



# Table of Contents

National Coordinator Letter .....	3
Statutory Requirement .....	4
Executive Summary .....	5
Introduction .....	8
Current State: Access, Exchange, and Use of EHI.....	9
Barriers to Progress .....	18
Actions Taken .....	23
Recommendations .....	44
Appendix A – 2020-2025 Federal Health IT Strategic Plan.....	45
References .....	46



# National Coordinator Letter

The United States (U.S.) health system has been on a path to becoming truly digital for over a decade. When Congress passed the Health Information Technology for Economic and Clinical Health Act (HITECH Act) in 2009, the health system lagged many other major economic sectors in the U.S. with respect to adopting digital information systems and lagged other industrialized countries with respect to using electronic health information (EHI) and adopting electronic health record (EHR) technology. Clinicians used pen and paper to capture important information from clinical encounters onto paper, which was stored in manila folders and file cabinets. The U.S. health system had limited information sharing for care coordination and offered few options for patients to easily access their health information.

Congress set the foundation for changing this paradigm by passing the HITECH Act in 2009 and the 21st Century Cures Act (Cures Act) in 2016. Since then, the healthcare and health IT industries have made tremendous progress. Most hospitals and clinicians now use EHRs, common data standards electronically capture clinical data, and routine sharing of EHI happens via interoperable [health information networks](#) and increasingly via modern application programming interfaces (APIs). However, this progress is not universal across the country and is affected by different priorities, resources, and business models among industry actors. Certain providers across the care continuum, such as long-term and post-acute care, hospice, some types of behavioral health providers, and home and community-based providers were ineligible for the incentive payments that HHS made to healthcare providers for the adoption and use of EHRs. These providers lag in EHR adoption and, thus, their ability to engage in interoperable exchange of EHI to support data sharing across the full spectrum of care.

The COVID-19 pandemic exposed many challenges in the nation's healthcare system, particularly the need for more reliable data, especially to support vulnerable individuals and those persistently marginalized. In addition, although significant funding under the HITECH Act propelled EHR adoption among hospitals and physician offices, until recently, our public health information technology (IT) systems had not received substantive resources. As a result, public health agencies were unable to make full use of certified health IT. Instead, public health agencies saw one-way data flows, overwhelmed public health data systems, and manual data review that led to limited actionable data for decision-making and no ability to provide real-time feedback to communities.

This report examines the current state of health IT adoption and EHI access, exchange, and use. As we collectively look toward the future, we should ask the question: What do we want to accomplish with the foundation built over the past decade? As National Coordinator, I will continue to work with partners in the public and private sectors to have health IT systems that serve *all* users' needs. Most importantly, this system should help us identify health inequities and facilitate interventions that remove the inequities and prevent them from turning into healthcare disparities. HHS will continue to focus on advancing interoperability, modernizing public health systems, reducing clinician burden, and accelerating the implementation of the Cures Act. I hope this report will provide an overview of all that has been accomplished in health IT, as well as HHS's commitment to ensuring every American can obtain their full health potential.

Micky Tripathi, Ph.D., M.P.P., National Coordinator for Health IT



# Statutory Requirement

Division A, Title XIII, Section 13113(a) of the American Recovery and Reinvestment Act of 2009, as part of the HITECH Act, requires the Secretary of Health and Human Services (HHS) to provide a report to Congress as follows:

(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.

This report is the latest update by the Secretary of HHS in fulfillment of section 13113(a). To review previous reports, please visit [www.healthit.gov](http://www.healthit.gov).



# Executive Summary

Over the past decade, healthcare in the U.S. has advanced with the use of health information technology (health IT) such that nearly all hospitals and physician offices transitioned from paper-based medical records to electronic health records (EHRs). This accomplishment established the foundation for consistent and secure access, exchange, and use of electronic health information (EHI). HHS regulations supporting care delivery and patient access through information sharing policies and ONC standards and technological requirements are modernizing how information sharing informs patients, caregivers, healthcare providers, and other members of care teams.

This report to Congress describes the progress made by the federal government and private sector to build a nationwide foundation for the access, exchange, and use of EHI, identifies barriers to such a nationwide foundation, and includes recommendations to improve the use of health IT to:

- Promote health and wellness;
- Enhance the delivery and experience of care; and
- Build a secure, data-driven ecosystem to accelerate research and innovation.

Additionally, this report serves as an update on the implementation progress of the [2020-2025 Federal Health IT Strategic Plan](#).

Continued implementation of the Cures Act, passed in 2016—as well as progress toward modernization of the U.S. public health data systems tested by the COVID-19 pandemic— supports patients, healthcare providers, health officials, health researchers, and innovators by creating a nationwide ecosystem to improve patient care and public health. The foundation is in place for patients, caregivers, healthcare providers, payers, public health practitioners, technology developers, and researchers to catapult the initial decade-long investment in health IT to enable better health for all.

## **Current State: Access, Exchange, and Use of EHI**

The interoperability of health IT systems steadily progressed in the past decade following a nationwide effort to obtain high adoption of certified EHRs among healthcare providers. Nearly all hospitals, ambulatory centers, and physicians' offices now use health IT certified under the ONC Health IT Certification Program. Patient access to electronic portals for viewing health information (portals) and health applications (apps) also continues to expand. As patients receive better access to their EHI, they can better manage their health and perform a variety of health-related tasks, such as viewing lab test results, scheduling appointments, and secure messaging with their healthcare providers.

The healthcare industry also made considerable progress toward interoperability of health IT systems by advancing exchange among health information networks to the point that numerous health information networks operate today at national and state/regional levels. While this is critical progress, additional steps are needed to advance network-to-network exchange to better serve the public interest. The Trusted Exchange Framework and Common Agreement (TEFCA) is leading that charge through a policy and technical infrastructure approach that builds on existing progress of networks and creates an



operational framework to enable secure information sharing when information needs to travel across the boundaries of networks or particular health IT systems. Patients see providers across practices, counties, and sometimes even states. The information sharing ecosystem must be able to support information being available to inform their care wherever they are seen.

Although tremendous progress has been made with EHRs that capture and support the use of health information about individuals, the COVID-19 pandemic exposed gaps in health IT systems that support capturing and using population data. The challenges exposed during the public health response to the COVID-19 pandemic pinpointed the importance of health IT to monitor population health regarding public health surveillance of testing, diagnosis, and vaccine distribution.

### **Barriers to Progress and Actions Taken**

The U.S. health system has made improvements in health IT and information sharing during the last decade. However, barriers exist that have resulted in uneven progress across healthcare and affected the ability to realize the full potential of certified health IT. This report includes recommendations for using current authorities, providing additional agency resources, and developing targeted innovations to overcome these barriers.

Specifically, this report focuses on barriers related to modernizing public health data systems, motivating the adoption of health IT and uniform nationwide network interoperability across the care continuum, supporting health equity, and advancing standards to support health information sharing across all care settings. This report also highlights the tremendous progress the U.S. has made to help mitigate the barriers mentioned above by improving the access, exchange, and use of EHI. The actions highlighted in this report are categorized into:

1. Prioritization of information sharing
2. Promotion of nationwide exchange across networks
3. Improvements in certified health IT and user experiences
4. Advancement of standards
5. Coordination of health IT efforts
6. Protection and security of EHI
7. Modernization of public health data systems
8. Support of health equity and comprehensive health and care needs
9. Advancement of health IT for research and data analytics

Although this report mainly focuses on actions taken by the federal government, contributions and collaboration across states, tribes, territories, local communities, and the private sector are also critical for progress toward a modern and connected health IT infrastructure.



## Recommendations

Health IT advancement to date has occurred on a foundation of widespread use of certified EHRs, supporting appropriate access, exchange, and use of EHI. The recommendations in this report aim to continue that progress and further support individuals, healthcare providers, payers, and public health agencies to use technology and health information to access their health data when they need it. The six recommendations are:

- Support “health equity by design” to include equitable access to information and communications technology, and improve health outcomes by building equity into the design of health IT.
- Coordinate with the Centers for Disease Control and Prevention (CDC) and other HHS agencies so that federal and state, tribal, local, and territorial (STLT) public health data systems are modernized using health IT standards that enable the collection, access, exchange, use, and reporting of public health data to prevent and mitigate public health threats.
- Promote the appropriate sharing of information by educating patients and the care community about [information blocking policy and regulations](#), track information blocking complaints, and coordinate with the HHS Office of Inspector General (OIG) and other HHS components on information blocking enforcement.
- Implement [TEFCA](#) to create a nationwide policy and technical infrastructure approach to better enable information sharing across health information networks.
- Advance standards to support health information sharing across all care settings, including APIs and the United States Core Data for Interoperability (USCDI), via certified health IT systems.
- Coordinate with federal agencies to ensure ONC-adopted standards support EHI access, exchange, and use across federal programs and health IT systems.



# Introduction

ONC is responsible for the implementation of certain provisions in Title IV of the Cures Act, including provisions related to the advancement of interoperability and the access, exchange, and use of EHI. The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (ONC Cures Act Final Rule) ([85 FR 25642](#)) (May 1, 2020) supports the requirements outlined in the Cures Act and aims to increase innovation and competition by fostering an environment where technology can enable hospitals, doctors, and others across the care continuum to work better together, allow patients to participate more directly in their own care, and catalyze the use of healthcare data to dramatically enhance value-based care, public health, and research. The final rule includes provisions supporting authorized users having access to EHI and creates certification criteria for standardized APIs, which will help increase business-to-business and business-to-consumer information sharing using modern internet technologies.

ONC coordinates across federal agencies to increase alignment of health IT functionalities, technical requirements (including health IT standards), and organizational policies and practices. This report to Congress describes the federal government's progress toward building a nationwide foundation for the access, exchange, and use of EHI and includes references to related progress made in the private sector. Additionally, this report serves as an update on the implementation progress of the [2020-2025 Federal Health IT Strategic Plan](#).

The health IT industry has progressed substantially in information sharing over the last decade. Policy and technical infrastructure needed for information sharing continues to become a reality for more and more people, including those who see healthcare providers in different healthcare systems or locations. Policies that support API standardization simplify information sharing between EHRs, other health IT systems, and mobile and internet-based applications. These initiatives are spurring the next phase in the decade-long investment in health IT—with patients, payers, public health practitioners, technology developers, and researchers using health IT to advance patient and population care in more seamless and inclusive ways.





# Current State: Access, Exchange, and Use of EHI

Through the passage of the HITECH Act in 2009, the launch of the Medicare and Medicaid EHR Incentive Programs (2010), and the passage of the Cures Act (2016), the U.S. has made tremendous progress in the use of standards that support interoperability among health IT systems, setting a solid foundation for the access, exchange, and use of EHI. Progress continues through implementation of the ONC Cures Act Final Rule—as well as a commitment to modernize the U.S. public health data systems that were stressed by the COVID-19 pandemic. Moving forward, it will be critical to focus on the secure, appropriate sharing of EHI wherever and whenever needed to improve healthcare quality, safety, efficiency, affordability, and equity.

## Health IT Adoption and Use

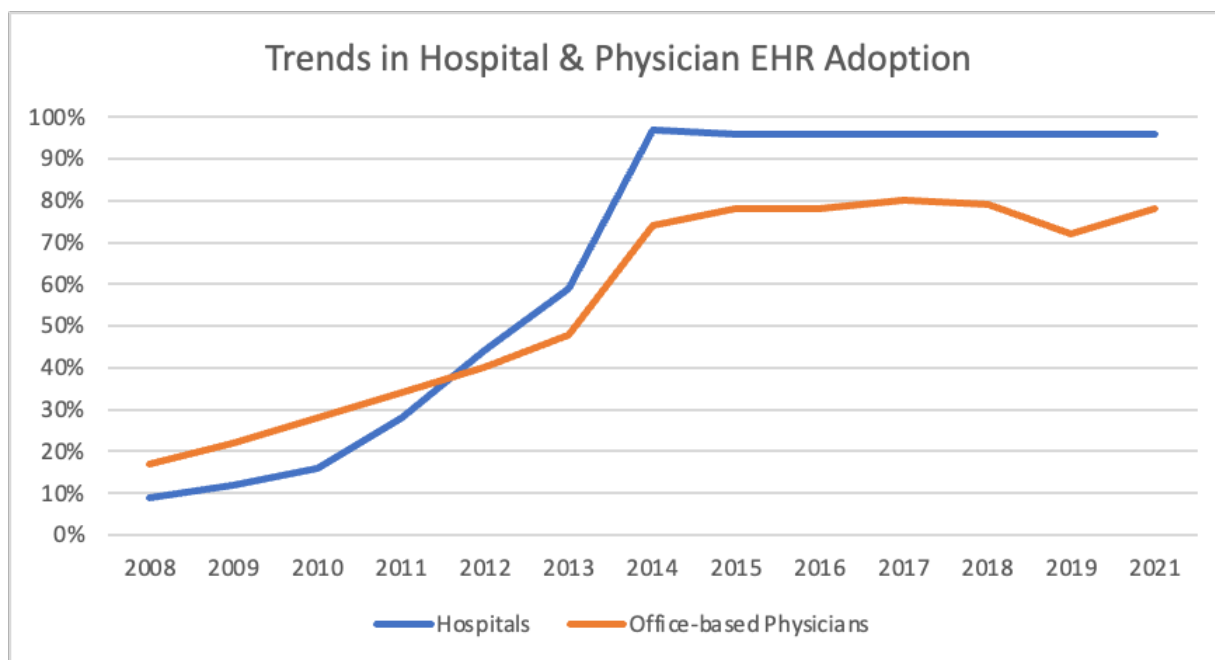
The interoperability of health IT has steadily progressed in the past decade following a national effort to lay a foundation of high adoption of EHRs among healthcare providers. As of 2021, nearly all non-federal acute care hospitals (96 percent) and nearly 4 in 5 office-based physicians have adopted a certified EHR. This marks substantial 10-year progress since 2011 when 28 percent of hospitals and 34 percent of physicians had adopted an EHR following the passing of the HITECH Act in 2010. (Figure 1).<sup>1</sup>

Adoption and use of certified health IT have been, and continue to be, necessary steps toward federal health IT goals, but there are additional activities needed, such as: modernizing public health data systems, motivating the adoption of health IT and uniform nationwide network interoperability across the care continuum, supporting health equity, and advancing standards to support health information sharing across all care settings to deliver on the promise of health IT to:

- Promote health and wellness;
- Enhance the delivery and experience of care; and
- Build a secure, data-driven ecosystem to accelerate public health, research, and innovation.



**Figure 1: Percentage of non-federal acute hospitals and physicians' offices that adopted an EHR 2008-2021.**



**Source:** AHA IT Supplement Survey for hospital EHR adoption; National Ambulatory Care Survey and National Electronic Health Record Surveys (NEHRS) for office-based physicians.

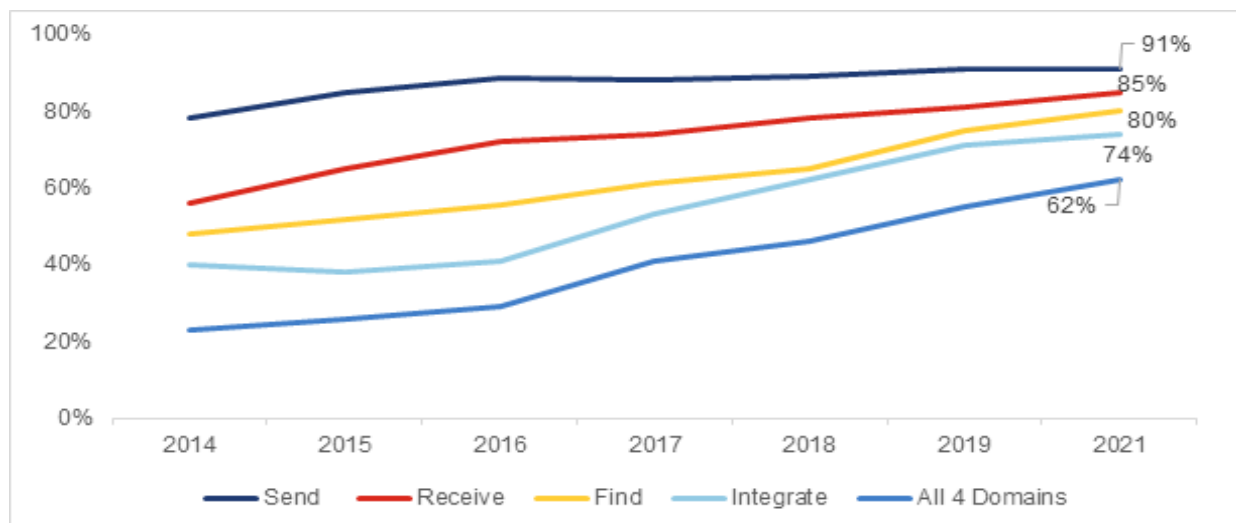
**Notes:** <sup>1</sup>In 2021, NEHRS results for office-based physicians showed a more consistent trend with data collected from 2015-2018, compared to 2019. We believe high rates of “Don’t know” responses to the 2019 survey question may have underestimated the rates of EHR adoption for that year. There was no survey in 2020.

### Health Information Exchange and Interoperability

The healthcare industry has made considerable progress toward interoperability by advancing health information exchange networks that focus on the exchange of data for treatment purposes, with numerous national and state/regional networks daily conducting tens of millions of secure medical record transactions for treatment. The information sharing and interoperability provisions of the Cures Act are critical accelerants of seamless and secure access, exchange, and use of EHI. Data shows that hospitals continue to lead the way with their steady progression of the four domains of interoperability, which consist of electronically sending, receiving, finding, and integrating (i.e., whether the EHR integrates summary of care record received electronically from providers or sources outside the hospital system/organization without the need for manual entry) health information into EHRs (Figure 2).<sup>2</sup>



**Figure 2: Percentage of non-federal acute hospitals engaging in electronically sending, receiving, finding, and integrating health information 2014-2021.**



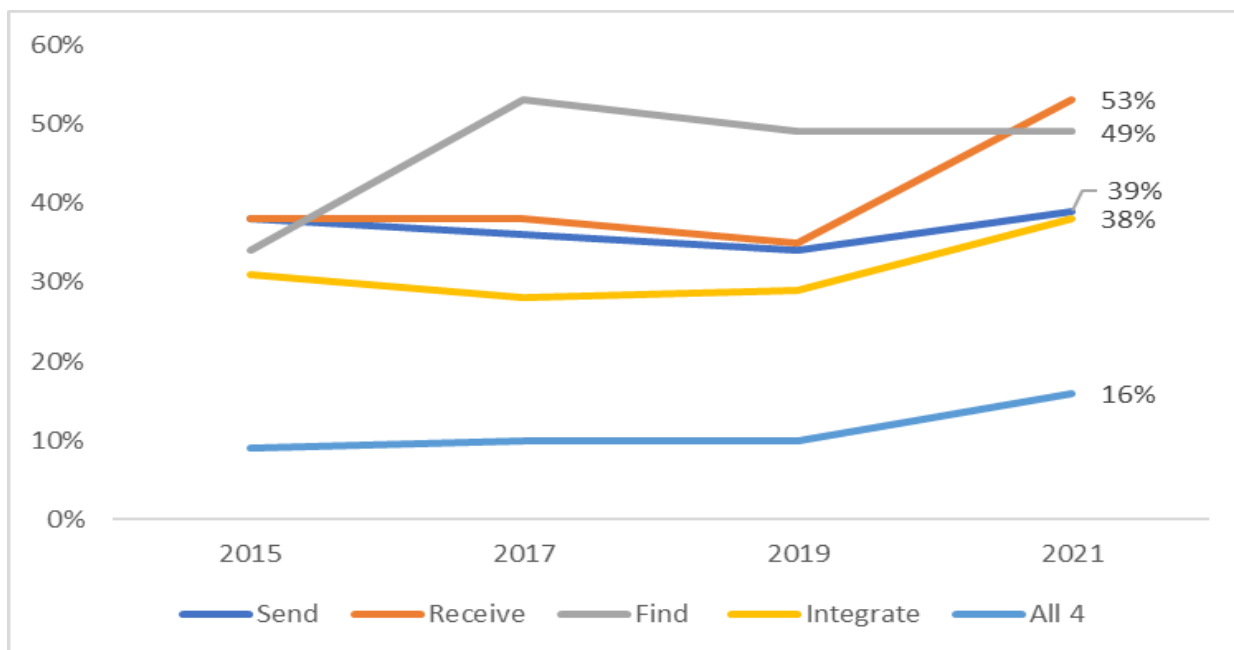
**Source:** 2014-2021 AHA Annual Survey Information Technology Supplement.

**Notes:** The four domains of interoperability consist of electronically sending, receiving, finding, and integrating into the EHR any health information.

In addition, the rates of physicians' engagement in electronically sending and integrating health information remained steady between 2015 and 2021. In 2021, across the four domains of interoperability, physician rates of electronically receiving (53 percent) and finding (49 percent) patient health information were the highest (Figure 3). Nearly two-thirds of physicians engaged in some form of electronic exchange—either sent, received, or queried patient health information—with providers outside of their organization in 2021. An overwhelming majority (over 75 percent) of physicians who engaged in Health Information Exchange (HIE) experienced improvements in quality of care, practice efficiency, and patient safety.<sup>3</sup>



**Figure 3: Percentage of physicians engaging in electronically sending, receiving, searching/querying, and integrating any health information 2015-2021.**



**Source:** National Electronic Health Record Survey, 2015-2021.

**Notes:** The four domains of interoperability consist of electronically sending, receiving, finding, and integrating into the EHR any health information.

Medium and large hospitals, non-critical access hospitals (CAHs), and hospitals in suburban and urban areas across the United States have the greatest participation in National, State, Regional, and Local Networks for health data exchange. The percentage of small, rural, and CAHs participating in each of these network types slightly lags compared to medium and large hospitals, suburban and urban hospitals, and non-CAHs respectively (Table 1).<sup>4</sup>

**Table 1: Percent of U.S. non-federal acute care hospitals that participate in national and state, regional, or local health information networks (HINs) by hospital type, 2021.**

Type of Network	Medium and Large	Small	Suburban and Urban	Rural	Non-CAH	CAH
State, Regional, or Local Network	79%	72%*	77%	73%*	77%	74%*
National Network	66%	61%*	67%	59%*	65%	62%*
Both Network Types	56%	49%*	56%	48%*	54%	50%*
Neither Network Type	13%	18%*	13%	18%*	14%	17%*

**Source:** 2021 AHA Annual Survey Information Technology Supplement.

**Notes:** \*Significantly different from a corresponding category presented in the column to the left ( $p < 0.05$ ); National network consists



of hospital participation in CommonWell Health Alliance, e-Health Exchange, Sequoia Project's Carequality, Strategic Health Information Exchange Collaborative (SHIEC), and EHR vendor networks.

Even with recent progress, there are components in the care continuum where progress lags. For example, payers and public health departments are not easily able to exchange health information to better support patients.

## **Patient Access to Their Health Information**

As patients receive better access to care and to their EHI, they can better manage their health and can be more active members of their care team. For example, CMS's expansion of access to care through telehealth services due to COVID-19 has allowed healthcare providers to increase access to care and to extend continuity of care options for their patients. These telehealth services provide support for people with chronic health conditions, reduce travel burden, help overcome physician shortages, especially in underserved or rural communities, screen and refer patients with symptoms of COVID-19, and reduce the spread of infectious diseases.<sup>5</sup> OCR has also supported patient access to their protected health information (PHI) through their HIPAA Right of Access Enforcement Initiative, which has resolved 43 investigations with resolution agreements, corrective action plans, and a monetary settlement, or a civil money penalty.

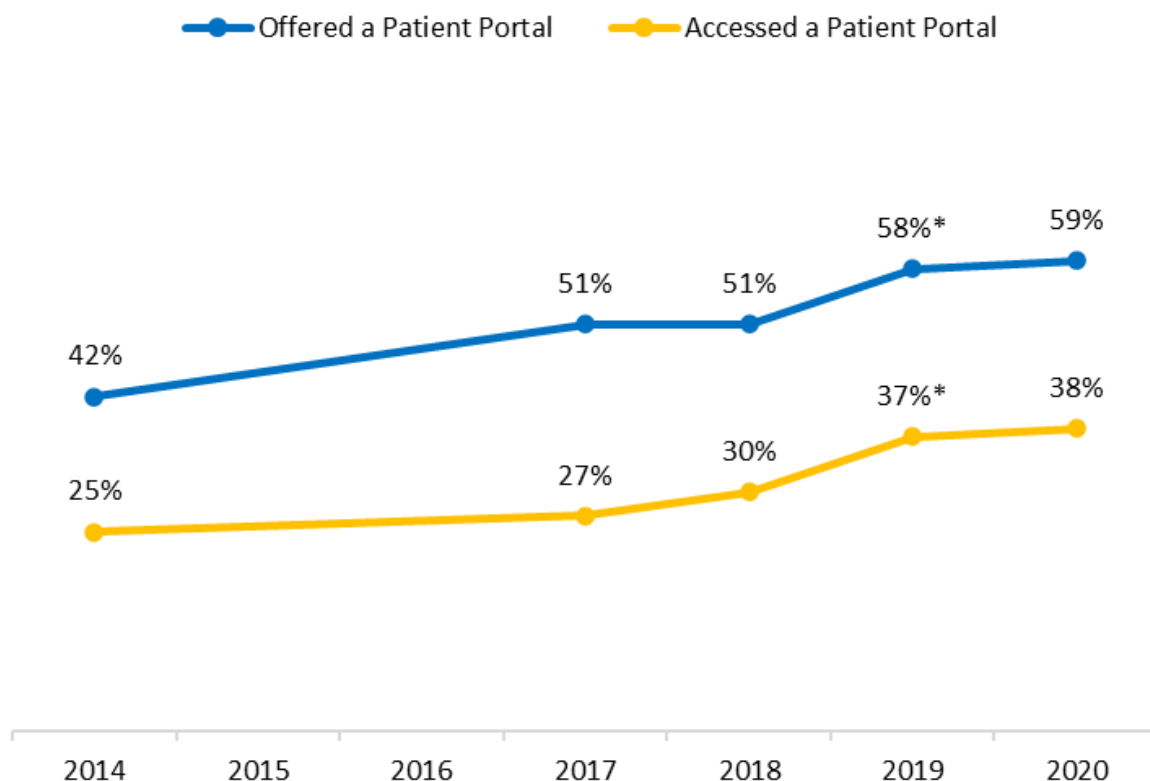
In addition, patient access to EHI is critical to patients having their most successful care journey. Patients use portals to manage their health and perform a variety of health-related tasks, such as viewing lab test results, scheduling appointments, and securely messaging with their healthcare providers. Three-quarters of hospitals reported enabling patients to view their providers' written clinical notes about the care they received. Patients' access to this data without unnecessary delay and their ability to perform health-related tasks using portals has advanced care delivery and would not have been possible without the investments over the last decade in EHRs and patient access to their EHI.

The percentage of patients who were offered, and accessed, a patient portal continues to trend upward (Figure 4).<sup>6</sup> Among individuals offered a patient portal, more than six in 10 accessed it at least once in 2020 – this represents an 11-percentage point increase from 2017.<sup>7</sup>

This upward trend suggests that providers' increased capabilities to provide patient access to their EHI has translated to increased availability and use of that information by patients.



**Figure 4: Percent of individuals nationwide who were offered and accessed a patient portal, 2014-2020.**



**Source:** HINTS 4 Cycle 4 (2014); HINTS 5, Cycles 1-4 (2017-2020).

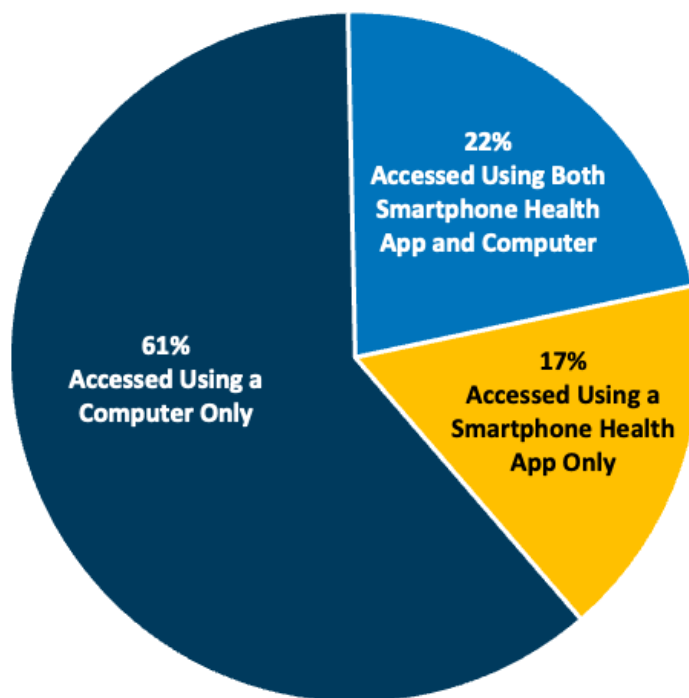
**Notes:** \*Significantly different from previous year ( $p < 0.05$ ). Denominator represents all individuals. Percentage reflects weighted national estimate for individuals offered a patient portal by a healthcare provider or insurer. The HINTS survey was not fielded in 2015 and 2016.

The ONC Cures Act Final Rule supports patient access to their health information by including a provision whereby patients are more likely to have access to their EHI without unnecessary delay and with greater respect for their needs and preferences. The ONC Cures Act Final Rule requires that certified health IT developers with Health IT Modules certified to certain certification criteria use API technology, which will help individuals to securely and easily access their EHI. Also, the ONC Cures Act Final Rule [defines information blocking](#), generally speaking, as a practice that if conducted by healthcare providers, developers of certified health IT, and health information networks and exchanges and such entity know, or should know, that such practice is likely to interfere with access, exchange, or use of EHI.

More than nine in 10 hospitals reported that they enabled inpatients to download their health information, and about three-quarters of hospitals reported their inpatients could electronically transmit their health information to a third party. A national survey reports in 2020 that almost two-thirds (60 percent) of individuals nationwide were offered access to their medical records (or patient portals) by a healthcare provider or insurer. Of those who were offered access in 2020, nearly 40 percent accessed their patient portals through a smartphone health app. In 2020, about one-third of patient portal users downloaded their data, nearly doubling since 2017.<sup>8</sup>



**Figure 5: Individuals Access and Use of Patient Portals and Smartphone Health Apps, 2020.**



**Source:** HINTS 5, Cycle 4 (2020).

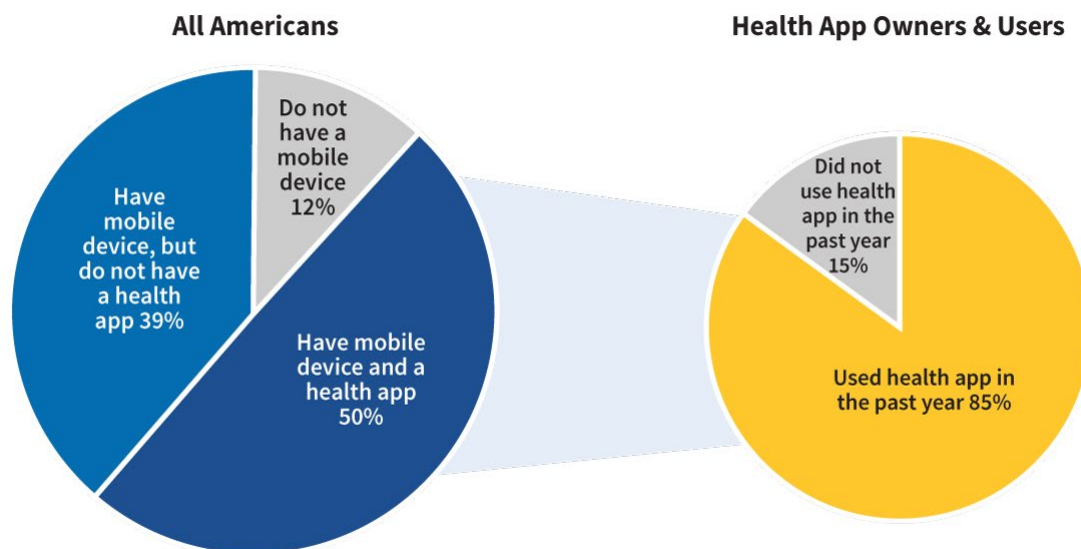
**Notes:** Denominator represents individuals who accessed their patient portals at least once within the past year. Individuals who access their portal at least once in the past year are referred to as “patient portal users.”

Data also indicates an increase in the availability of health apps that integrate with EHRs and patient portals. In 2019, 70 percent of hospitals enabled patients to access health information using apps, more than a 50 percent increase from 2018. Research also shows an increase in the number of apps that integrate with EHRs marketed for patients and providers. Between 2019 and 2020, the total number of unique apps in the five leading EHR app galleries increased from 600 to 734, with the most common types of apps being those intended for administrative (42 percent) and clinical (38 percent) use.<sup>9</sup>

Patient portal users most commonly access their health information through a computer (83 percent) – with six in 10 portal users accessing their health information using only this method. In 2020, about one in five patient portal users (22 percent) accessed their health information using both a smartphone health app and a computer and just under one in five patients (17 percent) accessed their health information through just their smartphone health app.<sup>10</sup>



**Figure 6: Percent of individuals who reported owning and using a mobile health app in the past year, 2020.**



**Source:** HINTS 5, Cycle 4 (2020)

As of 2020, 89 percent of Americans reported owning a tablet or smartphone and 50 percent reported having a mobile health app. Of those individuals who have a health app on their smart device, 85 percent reported using the app within the past year. In 2020, approximately seven in 10 individuals with a mobile health app also used it to track progress on a health-related goal.<sup>11</sup>

### Public Health Data Systems

Funding for EHRs through the HITECH Act over a decade ago was not accompanied by increases in funding for public health data systems. The medical and public health responses to the COVID-19 pandemic stressed the importance of health IT and the need for access, exchange and use of EHI to support healthcare providers, patients, caregivers, public health professionals, and researchers. During the COVID-19 pandemic, health IT supported:

- Public health surveillance and reporting;
- Laboratory testing;
- Clinical data collection;
- Case investigation; and
- Reporting patient outcomes.

The COVID-19 pandemic provided an opportunity for the rapid increase in electronic case reporting (eCR), which is an automated generation and transmission of case reports from EHRs to STLT public health agencies for review and action. eCR moves data quickly, securely, and seamlessly allowing healthcare and public health professionals to easily communicate back and forth.<sup>12</sup>





The CDC, with other federal agencies, vaccine providers, and STLT health facilities across the United States, tracks COVID-19 vaccine distribution and administration.<sup>13</sup> This major endeavor requires collaboration between public and private IT systems and integration of existing and newly developed IT systems. Immunization information systems (IIS) help providers and families by consolidating immunization information into one reliable source.

The CDC's [Data Modernization Initiative](#) (DMI) is a multi-year effort to modernize core data and surveillance infrastructure across the federal and STLT public health landscape. ONC and CDC are working together to ensure that DMI leverages the policy and technical advances promoted by the 21st Century Cures Act.



# Barriers to Progress

The healthcare industry has progressed substantially in information sharing. That said, in this highly fragmented healthcare system, progress is inconsistent and influenced by different priorities across industry actors. Addressing barriers to progress will help realize the full benefit to patients, healthcare providers, and the care ecosystem when data can be shared according to common standards. Below is a summary of barriers to progress that impact the advancement of interoperable health IT and a summary of actions taken by the federal government to address those barriers.

## Changing the Culture of Information Sharing

The information blocking provisions in the Cures Act bring motivation and consistency across the industry by authorizing appropriate disincentives to be imposed on healthcare providers and authorizing civil monetary penalties to be imposed on developers or offerors of certified health IT and health information networks/exchanges, that interfere with the access, exchange, and use of EHI. This significant change in law promotes a reconsideration of organizational information sharing policies and processes. However, the Cures Act [does not provide specific authority](#) for ONC or HHS to issue binding advisory opinions on whether a particular set of facts constitutes information blocking under the information blocking provisions.

Authorizing the issuance of binding advisory opinions would allow HHS to provide advice to requestors on how the information blocking provisions, including exceptions, apply to specific sets of facts. It would promote progress by increasing awareness regarding information blocking and requestor conduct that HHS has concluded is or is not consistent with the information blocking regulations. Such advisory opinions would give requestors that received favorable opinions confidence that their activities – within the specific confines of requests – are consistent with the information blocking regulations. Further, these advisory opinions could be published and disseminated broadly through available communication methods so that other entities could review them and apply the analysis to consider whether their own practices might be assessed if subject to HHS review.

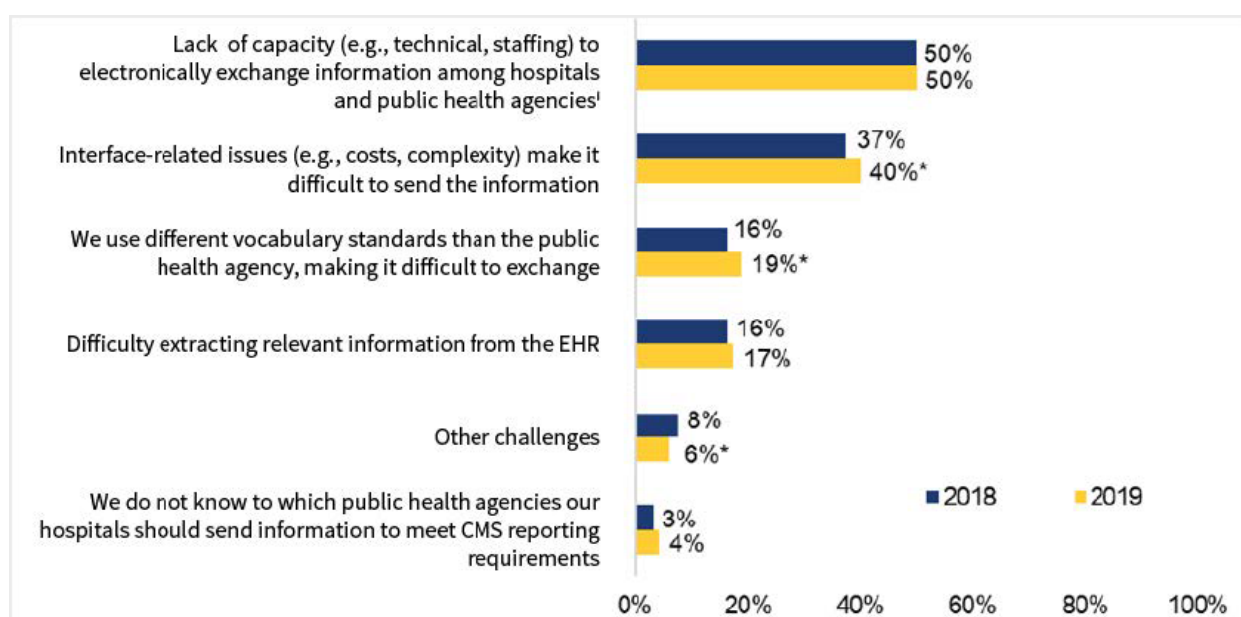
In addition to the information blocking provisions in the Cures Act, the U.S. healthcare system is continuing progress toward value-based care, in which payment is linked to measures of provider performance and patient outcomes and is based on evidence-based practices and guidelines. This movement is likely to continue and perhaps accelerate due to projected increases in healthcare spending. The shift to value-based care has created new incentives for providers in a variety of settings to improve quality and patient outcomes. These incentives place greater importance on addressing social determinants of health (SDOH) and patient health behaviors and engaging in preventive care, population health management, and disease management. Success in value-based payment models is contingent in part on healthcare provider and payer access to and exchange of population-level data that allows them to better understand the needs of their patients, stratify patients by risk, engage in patient outreach, and track outcomes over time. The access, exchange, and use of EHI play a fundamental role in the collection, reporting, and analysis of data needed to support value-based care.



## Need for Modern, Interoperable Public Health Data Systems

The demand for EHI sharing between clinical and public health systems during the COVID-19 pandemic created a renewed commitment among federal, state, local, and tribal governments to modernize the U.S. public health data systems. Clinical systems experienced various challenges, including a lack of capacity to exchange information and interface-related issues making it difficult to send information. Figure 7 identifies the public health reporting challenges experienced by non-federal acute care hospitals.<sup>14</sup> In 2019, 70 percent of non-federal acute care hospitals experienced one or more challenges with public health reporting. Small, rural, independent, and critical access hospitals were more likely to experience a public health reporting challenge compared to acute care hospitals.

**Figure 7: Types of Challenges Experienced by Non-Federal Acute Care Hospitals, 2018-2019.**



**Source:** 2019 AHA Annual Survey Information Technology Supplement.

**Notes:** Sample used for analyses includes non-federal acute care hospitals only and excludes 72 hospitals (1.6%) that didn't respond to any of the public health challenge questions. \*Significant association between challenges ( $p < 0.05$ ).

CMS requires hospitals to meet specific public health measures under the Promoting Interoperability Program. These measures include submission, and in some cases, receipt of, data for the purposes of immunization registries, syndromic surveillance reporting, electronic case reporting, and electronic reportable laboratory result reporting. Capabilities such as these benefit the public health landscape by increasing the timeliness and completeness of data and advancing disease surveillance.

Modernizing the U.S. public health data systems, including the use of standardized APIs and TEFCA, can help accelerate the information sharing capabilities that aid in public health. Such capabilities include more comprehensive and standardized reporting, bidirectional exchange for providers to receive targeted information from public health agencies, and advanced network capabilities to facilitate seamless information exchange among STLTs and with the CDC.



## Motivating the Adoption of Uniform Nationwide Network Interoperability

Each day, nationwide health information networks facilitate the secure exchange of tens of millions of clinical documents, and state/regional HIEs provide local interoperability services around the country. However, some significant gaps remain. Healthcare providers face many challenges when exchanging information across different care settings or organizations, particularly across different data platforms (Table 2). Most state/regional HIEs serve only their local markets with many unconnected to other networks. This presents barriers to better care, higher costs to the healthcare system, and a diminished user experience for patients and healthcare providers.

Market competitors in health IT face complex business, legal, and technical issues that require agreement on common solutions to ensure information exchange between entities. Among hospitals, for example, the most cited barriers to sending and receiving information do not relate to the hospital's IT but rather to their partners' IT: 64 percent of hospitals indicate their partners' EHRs lack the capability to receive data, and 67 percent of hospitals indicate providers with whom they share patients do not share data with them (Table 2).

Aligning technical standards supports information sharing through certified health IT systems using APIs and USCDI. These standards are part of the ONC Cures Act Final Rule for certified health IT and underpin TEFCA. Following the release of USCDI version 3, USCDI now includes a standardized set of 19 data classes and 95 data elements that provide clearer direction toward the standardized, electronic exchange of social determinants of health and public health data. Additional updates are now under consideration in [draft USCDI version 4](#).

**Table 2: Percent of U.S. non-federal acute care hospitals that experienced barriers when trying to electronically send, receive, or find health information to/from other care settings or organizations, 2021.<sup>15</sup>**

Barriers related to electronically <u>sending</u> patient health information	Percent
Exchange partners' EHR system lacks capability to receive data	64%
Exchange partners we would like to send data to do not have an EHR or other electronic system to receive data	52%

Barriers related to electronically <u>receiving</u> patient health information	Percent
There are providers with whom we share patients who don't typically exchange patient data with us	67%
Difficult to match or identify the correct patient between systems	57%

Other barriers related to exchanging patient health information	Percent
Greater challenges exchanging data across different vendor platforms	72%
Develop customized interfaces to electronically exchange health information	54%

Source: 2021 AHA Annual Survey Information Technology Supplement.



**Table 3: Among physicians engaged in HIE, percent who reported barriers to HIE, 2019.<sup>16</sup>**

Barriers to Exchange	Percent
Electronic exchange with providers using a different EHR vendor is challenging	85%
Electronic exchange involves using multiple systems or portals	73%
Providers in our referral network lack the capability to electronically exchange	71%
It is difficult to locate the electronic address of providers	56%
Electronic exchange involves incurring additional costs	55%

**Source:** National Electronic Health Record Survey, 2019.

**Notes:** Estimated on the sample of providers who electronically send, receive, or search/query patient health information (65% of respondents). The sample includes physicians who marked 'not applicable' in their responses to the questions in the denominator. In the section Benefits of Exchange, the numerator consists of respondents who marked "strongly or somewhat agree" while in section 'Barriers to Exchange', the numerator consists of respondents who marked 'yes' to corresponding items.

### Significant Gaps in Health IT Adoption and Electronic Health Information Sharing Across the Care Continuum

While health IT adoption has substantially increased over the last decade, gaps remain in health IT adoption and EHI sharing across the care continuum. The HITECH Act authorized HHS to establish the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs to encourage eligible professionals (EPs), eligible hospitals, and CAHs to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology (CEHRT) now known as the [Promoting Interoperability Program](#), but it did not include incentives for all professionals across the care continuum (e.g., some types of behavioral health professionals, long-term and post-acute care, hospice, and home and community-based providers). Although some health IT adoption has occurred, interoperability in long-term and post-acute care settings remain low, and fewer than one in 10 substance abuse centers use electronic methods to send or receive client information.<sup>17</sup> While 96% of non-federal acute care hospitals have implemented certified EHRs, other hospital types have lower adoption rates. For instance, [59% of long-term \(acute\) care hospitals](#) and only half of psychiatric hospitals possess this technology.<sup>18</sup>

These providers face significant barriers to achieving and realizing the benefits of health IT adoption due to associated costs and limited financial incentives.<sup>19</sup> Interoperability can improve transitions of care between acute-care and post-acute care facilities, such as skilled nursing facilities (SNFs) and home health agencies.<sup>20</sup>

While most behavioral health providers did not receive HITECH Act funding for certified health IT, this segment of the care continuum has progressed with adoption of health IT. However, significant gaps remain in comprehensiveness of adoption by health IT function and facility-type.<sup>21</sup> Most progress has been in core health IT functions (e.g., storing records electronically), while adoption of interoperability and patient engagement technologies is considerably lagging.<sup>22</sup> Currently, standards do not exist for sharing patient-generated data, such as wearable device data or self-test results. Standardized methods for patients to share this data with their healthcare providers and EHRs are needed. As a result, challenges exist for exchanging critical patient information in a timely and standardized manner across healthcare settings, and with payers, patients, and caregivers, as well as with home and community-based service



providers. Additionally, social determinants of health—the conditions in which people live, learn, work, and play<sup>23</sup>—can contribute to disparities that impact the capture and exchange of patient information.



# Actions Taken

The U.S. healthcare system has made significant strides toward building a more modern health IT infrastructure that can benefit all users. Actions of federal agencies, such as HHS implementation of the Cures Act, are propelling the healthcare system toward improved access, exchange, and use of EHI.

As the nation continues its response to the challenges presented by the COVID-19 pandemic, the need for technology and access, exchange, and use of EHI to support a variety of health IT users has never been greater. Although this report mainly focuses on specific actions taken by the federal government, contributions and collaboration across states, tribes, communities, and the private sector are also critical for progress toward a modern and connected health IT infrastructure.

## PRIORITIZATION OF INFORMATION SHARING

Health IT certified under the ONC Health IT Certification Program is used by hundreds of thousands of physician offices, hospitals, and health systems across the U.S. As a result, the federal government and private sector have increased their focus on improving interoperability—the secure exchange of EHI with, and use of EHI from, other health IT entities without special effort on the part of the user.<sup>24</sup>

### Promoted the Interoperability of EHI

HHS promoted interoperability of EHI through regulations released in tandem—the ONC Cures Act Final Rule and [CMS Interoperability and Patient Access Final Rule](#). The ONC Cures Act Final Rule established an API certification criterion, which requires the use, for health IT certified to the criterion, of the Health Level 7 (HL7<sup>®</sup>) Fast Healthcare Interoperability Resources (FHIR<sup>®</sup>) standard Release 4.0.1 and references several standards and implementation specifications adopted in 45 CFR § 170.213 and § 170.215 to support standardization and interoperability. This certification criterion will help align industry efforts around HL7<sup>®</sup> FHIR<sup>®</sup> Release 4.0.1 and advance interoperability of API-enabled “read” services for single and multiple patients. The CMS Interoperability and Patient Access Final Rule requires CMS-regulated payers to implement and maintain a secure, standards-based (HL7<sup>®</sup> FHIR<sup>®</sup>) Patient Access API.

The ONC Cures Act Final Rule focused on providing access to EHI among healthcare technology users (including patients), updating the ONC Health IT Certification Program and 2015 Edition Certification Criteria, and addressing information blocking. This groundbreaking regulation was designed to overcome barriers to the appropriate sharing of EHI and support seamless access, exchange, and use of EHI.

The ONC Cures Act Final Rule also emphasized the importance of sharing health data in a secure way by adding certification criteria to include Encrypt Authentication Credentials and Multi-Factor



Authentication attestations.<sup>1</sup> These criteria allow developers of certified health IT to attest (yes or no) to whether their Health IT Module encrypts stored authentication credentials and whether their Health IT Module supports the authentication (e.g., two-factor/multi-factor authentication that verifies user's identity using multiple methods of authentication, such as a username and password, which then directs the user to a one-time generated security code) of the user's identity with the use of industry-recognized standards. Together, these certification criteria provide visibility on which certified health IT developers are using industry best practices to encrypt and secure health data.

The CMS Interoperability and Patient Access Final Rule required payer use of APIs to improve the electronic exchange of healthcare data in specific areas and modified the conditions of participation to require hospitals—including psychiatric hospitals and critical access hospitals (CAHs)—capable of doing so, to send electronic patient-event notifications of a patient's admission, discharge, and/or transfer to another healthcare facility or to another community provider or practitioner, under certain conditions.

Additionally, CMS issued the Advancing Interoperability and Improving Prior-Authorization Processes [proposed rule](#), (CMS-0057-P) (87 FR 76238, December 13, 2022), open for public comment until March 13, 2023. The proposed rule would improve patient and provider access to health information and streamline processes related to prior authorization for medical items and services. CMS proposes to modernize the health care system by requiring certain payers to implement and maintain an API to facilitate the electronic prior authorization process, shorten the time frames for certain payers to respond to prior authorization requests, and establish policies to make the prior authorization process more efficient and transparent. The rule also proposes to require certain payers to implement APIs that would enable data exchange from one payer to another payer when a patient changes payers or has concurrent coverage. CMS' proposed requirements reference standards adopted by ONC to support interoperability in the ONC Cures Act Final Rule; these standards include the USCDI and FHIR Release 4. In January 2022, ONC released a request for information ([87 FR 3475](#)) about how updates to standards and certification criteria in the ONC Health IT Certification Program could support prior authorization initiatives undertaken by CMS.

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<sup>1</sup> 45 CFR § 170.315(d)(12) *Encrypt authentication credentials*. Health IT developers must make one of the following attestations and may provide the specified accompanying information, where applicable:

- (i) Yes – the Health IT Module encrypts stored authentication credentials in accordance with standards adopted in § 170.210(a)(2).
- (ii) No – the Health IT Module does not encrypt stored authentication credentials. When attesting “no,” the health IT developer may explain why the Health IT Module does not support encrypting stored authentication credentials.

45 CFR § 170.315 (d)(13) *Multi-factor authentication*. Health IT developers must make one of the following attestations and, as applicable, provide the specified accompanying information:

- (i) Yes – the Health IT Module supports the authentication, through multiple elements, of the user's identity with the use of industry-recognized standards. When attesting “yes,” the health IT developer must describe the use cases supported.
- (ii) No – the Health IT Module does not support authentication, through multiple elements, of the user's identity with the use of industry-recognized standards. When attesting “no,” the health IT developer may explain why the Health IT Module does not support authentication, through multiple elements, of the user's identity with the use of industry recognized standards.





## Advanced Information Sharing through Information Blocking Regulations

In the ONC Cures Act Final Rule, ONC identified [eight reasonable and necessary activities](#) (referred to as “exceptions”) that do not constitute information blocking, provided certain conditions within each exception are met. The exceptions support seamless and secure access, exchange, and use of EHI and offer [actors](#)—healthcare providers, health IT developers of certified health IT, health information exchanges (HIEs), and health information networks (HINs)—certainty that practices that meet the conditions of an exception will not be considered information blocking.

The ONC Cures Act Final Rule, which included enhancements to the ONC Health IT Certification Program as well as establishing the information blocking regulatory provisions, helped improve individual access to usable health information and enabled healthcare providers, researchers, and public health agencies to more freely use health IT to improve healthcare. The ONC Cures Act Final Rule helped reduce barriers that have prevented new developers from entering and competing in the marketplace. It promoted the use of secure, standards-based APIs that encourage the development of health apps that provide access to and use of data in EHRs and improve the portability of health information to reduce costs associated with transitioning to new certified health IT systems and other health IT.

As of April 5, 2021, the information blocking regulations applied to all actors, as noted above. Actors found to have committed information blocking are subject to the following:


- Health IT developers of certified health IT, HINs, and HIEs: Civil monetary penalties (CMPs) as much as \$1 million per violation; and
- Healthcare providers: Appropriate disincentives to be established by the Secretary of Health and Human Services.

The information blocking regulations support an environment for the appropriate sharing of EHI, and ONC created a publicly available [comprehensive information blocking resource](#). ONC has released fact sheets on a range of topics related to the information blocking regulations that included summaries of the eight information blocking exceptions, background on the actors subject to the information blocking regulations, and highlighted regulatory dates and timelines for implementation. ONC continues to actively engage with communities of health IT users and appreciates feedback and questions, as the inquiries ONC receives help inform the development of resources that will be made publicly available on [www.healthit.gov](http://www.healthit.gov).



Figure 8: *ONC Information Blocking Resources through January 31, 2023.*



 [Information Blocking Frequently Asked Questions \(FAQs\)](#) includes the link to [ONC’s Information Blocking Portal](#) where individuals or entities can submit an information blocking claim.

The HHS Office of Inspector General (OIG) has the authority to review and investigate claims of potential information blocking against healthcare providers, health IT developers of certified health IT, and HINs/HIEs. ONC created a [Quick Stat](#) on the information blocking claims received through the Report Information Blocking Portal beginning on April 5, 2021—the applicability date of the [information blocking regulations](#). From April 5, 2021 – October 31, 2022, ONC received 535 [information blocking claims](#).

### Empowered Patients and Healthcare Providers

Policies promoting the use of secure, standards-based APIs, including regulations established to implement the Cures Act, encourage the development of health apps that provide access to and use of data in EHRs to better support person-centered care and patient empowerment.

The ONC Cures Act Final Rule requires that developers of certified health IT with Health IT Modules certified to particular certification criteria publish APIs to minimize the “special effort” necessary to access, exchange, and use EHI. The final rule supported and strongly encourages providing individuals with information that will assist them in making the best choice for themselves in selecting a third-party application ([85 FR 25815](#)), with patient authentication using a protocol called [OAuth 2](#) security standard to keep EHI private and secure. OAuth 2 provides a more secure approach to authorization over the internet by avoiding the sharing of login credentials with applications/services. The app(s) selected by the patient should be able to access and deliver the information securely from the patient’s medical records.

The ONC Cures Act Final Rule noted that an actor, such as a healthcare provider, can inform an individual about the advantages and disadvantages of exchanging EHI and any associated risks, so long as the information communicated is accurate and legitimate. An actor cannot mislead an individual about the nature of the consent to be provided, dissuade individuals from providing consent in respect of disclosures to the actor’s competitors, or impose onerous requirements to effectuate consent that are



unnecessary and not required by law, without potentially implicating the information blocking provision ([85 FR 25815](#)).

In addition, the ONC Cures Act Final Rule provided examples illustrating how, without being likely to engage in information blocking, certified health IT developers might provide factually accurate, unbiased information about apps' privacy policies and practices to help the patient make a more informed choice of which apps to use to receive their EHI ([85 FR 25815](#)). [Recent ONC research](#) found that the number of apps integrating with certified EHRs increased by more than 20 percent in 2020.<sup>25</sup>

## PROMOTION OF NATIONWIDE EXCHANGE ACROSS NETWORKS

Progress on the use of certified health IT by healthcare providers helped facilitate greater interoperability for several clinical health information purposes. The healthcare industry has also made considerable progress toward interoperability by advancing exchange networks, and numerous networks operate today at national, state, and regional levels. However, there is still a need for a policy and technical infrastructure approach to ease information sharing across networks and other health IT systems.

### Trusted Exchange Framework and Common Agreement (TEFCA)

In January 2022, ONC and its Recognized Coordinating Entity (RCE), The Sequoia Project, Inc., released TEFCA, fulfilling the Cures Act requirement. The Trusted Exchange Framework ([87 FR 2800](#)) presented a common set of non-binding principles for policies and practices to facilitate data-sharing among HINs. The Common Agreement is the legal contract the RCE signs with each qualified health information network (QHIN). This agreement defines baseline legal and technical requirements for secure information sharing nationwide and advances the principles in the Trusted Exchange Framework.

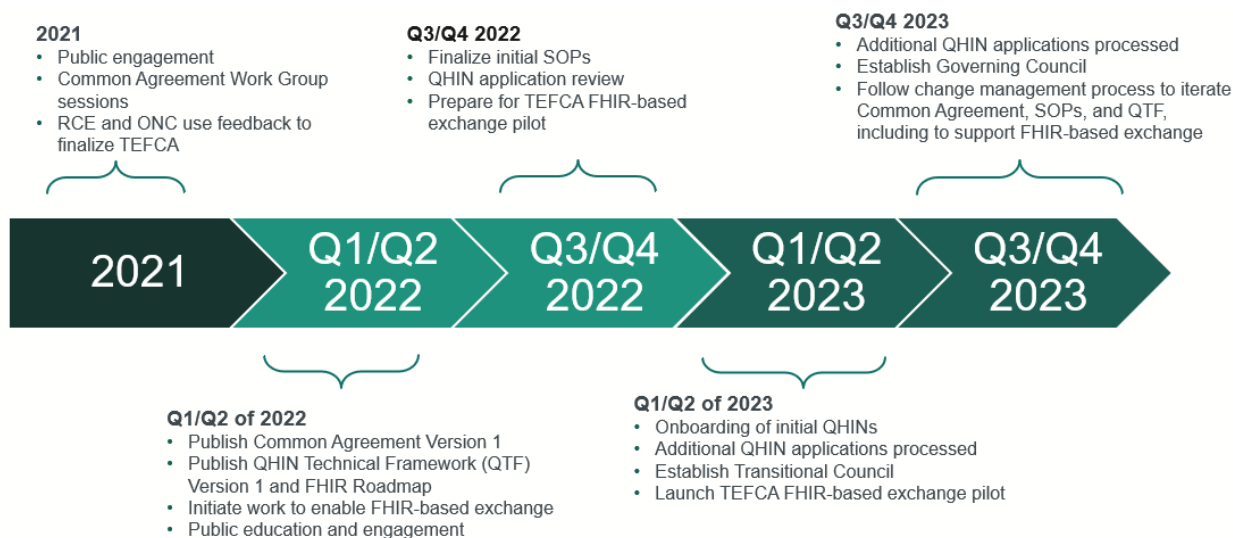
TEFCA will enable the appropriate sharing of EHI between networks to:

- Increase secure and appropriate access to data, which will better support existing use cases that HINs and health IT developers have enabled for their users;
- Ensure that a core set of data will be available among networks connected through the Common Agreement for the following exchange purposes: treatment, individual access services, public health, benefits determinations, a subset of the HIPAA-defined payment activities (utilization review), and a subset of the HIPAA-defined health care operations (quality assessment and improvement, business planning and development);
- Decrease costs and improve efficiency by reducing or eliminating the need to join multiple HINs and multiple legal agreements, or the need to create one-off, point-to-point interfaces; and
- Provide HINs and health IT developers with a common set of privacy and security requirements for the purpose of protecting patient data

To implement TEFCA and enable nationwide exchange of health data across various HINs and other entities, ONC continues to work with federal partners, the RCE, and private organizations.



**Figure 9: Timeline to Operationalize TEFCA**



## IMPROVEMENTS IN CERTIFIED HEALTH IT AND USER EXPERIENCES

Nearly all non-federal acute care hospitals and about three-quarters of office-based physicians use health IT certified via the ONC Health IT Certification Program. ONC continues to advance the development and use of health IT capabilities and improve the experience of users through this program.

ONC established the [2015 Edition Health IT Certification Criteria](#) in 2015, and in 2019, CMS required it in the [Promoting Interoperability Programs and the Merit-based Incentive Payment System Promoting Interoperability performance category](#). A recent study evaluated how changes between the 2014 and 2015 editions of Health IT Certification Criteria affected interoperability among non-federal acute care hospitals.<sup>26</sup> The findings indicated significant improvements in interoperability, especially in find/query health information and jointly in four domains (send, receive, integrate summary of care records, and find/query health information), increasing the latter by 18 percent.

Figure 10: Understanding Certified Health IT

The Office of the National Coordinator for Health Information Technology

Browse criteria by clicking an icon from the wheel.

Interoperability is essential for systems to communicate

ONC Certified HIT

Certification supports clinician engagement in clinical practice improvement and care coordination activities using health IT – including participation in CMS programs

2015 Edition Certification Criteria Categories

- CLINICAL PROCESSES
- CARE COORDINATION
- CLINICAL QUALITY MEASUREMENT
- PRIVACY & SECURITY
- PATIENT ENGAGEMENT
- PUBLIC HEALTH
- HEALTH IT DESIGN & PERFORMANCE
- ELECTRONIC EXCHANGE

Patients can access and send their health information electronically

Clinicians & Hospitals have tools for clinical processes, care coordination, and quality improvement

Developers can assure their customers that their product meets recognized standards and functionality

**About the Certification Criteria**

There are fifty-eight 2015 Edition health IT certification criteria, which are organized into the eight categories specified on the wheel above. ONC-Authorized Certification Bodies (ONC-ACBs) certify health IT products that have been successfully tested by an ONC-Authorized Testing Laboratory (ONC-ATL) to the certification criteria. These products are then listed on the Certified Health IT Product List (CHPL). We encourage clinicians to work with their health IT developers to determine if their products include the right set of certified functionality to support their practices and patients.

Learn More

2015 Edition Final Rule | Cures Act Final Rule

The ONC Cures Act Final Rule introduced two new technical certification criteria necessary to implement the Cures Act.

- The EHI Export criterion (45 CFR § 170.315(b)(10)) focuses on the ability to export the EHI stored in and by certified health IT to support both patient EHI access requests and healthcare provider export requests, allowing a user to execute this capability at any time the user chooses and without subsequent developer assistance to operate; and
- Standardized API for Patient and Population Services criterion (45 CFR § 170.315(g)(10)) requires the use of the HL7® FHIR® Release 4 standard and several implementation specifications. Two types of API-enabled services are required: services for which a single patient’s data is the focus, and services for which multiple patients’ data are the focus. This allows providers to share individual or population-level data, as needed.

These criteria can improve patients’ and healthcare providers’ experience with moving data across different health IT systems for providers who utilize certified health IT. For example, a provider with a Health IT Module certified to these criteria can more effectively respond to a patient’s request for all their information, or a healthcare provider could more easily migrate information on all their patients from one health IT system to another.



## EHR Reporting Program

In December 2021, ONC completed extensive community engagement to inform the development of the EHR Reporting Program as required by section 4002(c) of the Cures Act, which added section 3009A to the Public Health Service Act. ONC intends to propose through [rulemaking](#) provisions to implement the Cures Act requirement to establish the EHR Reporting Program.

## ADVANCEMENT OF STANDARDS

Standards are agreed-upon methods for connecting systems together and helping to move EHI across different technologies including EHRs, medical devices, and HINs. Using data elements consistently and reliably allows for collecting information for individual health needs as well as for reuse of that information to drive decision support, quality measurement and reporting, population health management, public health, and research.

The federal government participates in industry processes to advance health IT standards, such as through standards development organizations (SDOs). Also, the federal government uses its authorities and investments to coordinate accelerated standards maturity, adoption, and use. ONC coordinates the identification, assessment, and determination of "recognized" interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs. These authorities include ensuring that health IT certified through the ONC Health IT Certification Program provides end users with confidence that the technology they depend on to provide care lives up to its certified capabilities.

The National Library of Medicine (NLM) at the National Institutes of Health (NIH) works as a central coordinating body within the Department of Health and Human Services to support the development, maintenance, and dissemination of terminology and other health standards that promote interoperability among EHR systems, as well as other clinical and research information systems.

In addition, ONC required through rulemaking certain standards for health IT certified to the API certification criterion (e.g., HL7® FHIR®, USCDI) and released Standards Bulletins to inform the health IT community about standards development and availability. For example, the ONC Standards Bulletin 2022-2 (SB22-2) discusses the latest USCDI Version 3 that includes two new data classes and 24 new data elements consistent with the Executive Orders on Advancing Racial Equity and Support for Underserved Communities through the federal government and [Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats](#).

### The United States Core Data for Interoperability (USCDI)

[USCDI](#) is a core set of standardized health data for interoperable health information exchange across care settings. USCDI defines a common set of data that are needed for a wide range of use cases. These standardized data are regularly exchanged within and between certified health IT and are increasingly exchanged within and across other environments (e.g., data registries, data repositories, and consumer-facing apps). USCDI informs interoperable health IT implementations, such as for federal agencies supporting health and health care, hospitals, research organizations, clinician offices, and software developers. Further, USCDI is effectively the minimum dataset of the health system because:



- Certified health IT systems certified to certain certification criteria must be capable of exchanging USCDI data. As a result, the list of data elements in USCDI has become the floor of what data are available via the health IT systems of most hospitals and doctors' offices.
- TEFCA (and other major interoperability and state HIEs) requires exchange of the USCDI dataset, and users have noted that gaps exist for common standards for exchanging data not within the USCDI dataset.
- Major consumer health apps are using USCDI to give consumers online access to EHI.

ONC organizes USCDI by data elements and classes. A data element's use is not bound by its data class title. Furthermore, a data class title does not define the workflow where the data elements are collected and used. Data classes are aggregations of data elements organized by a common theme. Data elements are not bound by their data classes and can be used to describe other data elements in other data classes. USCDI includes widely adopted code sets as Applicable Vocabulary Standards that are supported by NLM and are important to the interoperable exchange of electronic health data, such as, RxNorm for medications, SNOMED CT U.S. Edition for clinical terminology, and LOINC for observations, tests and measurement.

ONC updates the USCDI regularly to keep pace with medical, technology, and policy advancements.

- USCDI Version 1 (February 2020) and [updated USCDI Version 1](#) (July 2020 Errata). The ONC Cures Act Final Rule required certified health IT developers to support USCDI Version 1 in certain of their products. Some of the data classes included in USCDI Version 1 are Laboratory, Medications, and Clinical Notes.
- [USCDI Version 2](#) (July 2021) included new data elements that provide guidance toward the standardized, electronic exchange of data about sexual orientation, gender identity, and SDOH.
- [USCDI Version 3](#) (July 2022) and updated USCDI Version 3 (October 2022 Errata) expanded on Version 2 by adding 24 data elements across the following data classes: Health Insurance Information, Health Status/Assessments, Laboratory, Medications, Patient Demographics/Information, and Procedures.
- [Draft USCDI Version 4](#) (January 2023) expands on USCDI Version 3 by proposing 20 new data elements and one new data class: Substance (non-medication).





Figure 11: New Data Classes and Elements in USCDI v3.

<b>Allergies and Intolerances</b> <ul style="list-style-type: none"> <li>Substance (Medication)</li> <li>Substance (Drug Class)</li> <li>Reaction</li> </ul>	<b>Clinical Tests</b> <ul style="list-style-type: none"> <li>Clinical Test</li> <li>Clinical Test Result/Report</li> </ul>	<b>Health Status/ Assessments</b> <ul style="list-style-type: none"> <li>Health Concerns</li> <li>Functional Status</li> <li>Disability Status</li> <li>Mental Function</li> <li>Pregnancy Status</li> <li>Smoking Status</li> </ul>	<b>Patient Demographics/ Information</b> <ul style="list-style-type: none"> <li>First Name</li> <li>Last Name</li> <li>Middle Name (Including middle initial)</li> <li>Name Suffix</li> <li>Previous Name</li> <li>Date of Birth</li> <li>Date of Death</li> <li>Race</li> <li>Ethnicity</li> <li>Tribal Affiliation</li> <li>Sex</li> <li>Sexual Orientation</li> <li>Gender Identity</li> <li>Preferred Language</li> <li>Current Address</li> <li>Previous Address</li> <li>Phone Number</li> <li>Phone Number Type</li> <li>Email Address</li> <li>Related Person's Name</li> <li>Related Person's Relationship</li> <li>Occupation</li> <li>Occupation Industry</li> </ul>	<b>Procedures</b> <ul style="list-style-type: none"> <li>Procedures</li> <li>SDOH Interventions</li> <li>Reason for Referral</li> </ul>
<b>Assessment and Plan of Treatment</b> <ul style="list-style-type: none"> <li>Assessment and Plan of Treatment</li> <li>SDOH Assessment</li> </ul>	<b>Diagnostic Imaging</b> <ul style="list-style-type: none"> <li>Diagnostic Imaging Test</li> <li>Diagnostic Imaging Report</li> </ul>			<b>Provenance</b> <ul style="list-style-type: none"> <li>Author Organization</li> <li>Author Time Stamp</li> </ul>
<b>Care Team Member(s)</b> <ul style="list-style-type: none"> <li>Care Team Member Name</li> <li>Care Team Member Identifier</li> <li>Care Team Member Role</li> <li>Care Team Member Location</li> <li>Care Team Member Telecom</li> </ul>	<b>Encounter Information</b> <ul style="list-style-type: none"> <li>Encounter Type</li> <li>Encounter Diagnosis</li> <li>Encounter Time</li> <li>Encounter Location</li> <li>Encounter Disposition</li> </ul>	<b>Immunizations</b> <ul style="list-style-type: none"> <li>Immunizations</li> </ul>		<b>Unique Device Identifier(s) for a Patient's Implantable Device(s)</b> <ul style="list-style-type: none"> <li>Unique Device Identifier(s) for a patient's implantable device(s)</li> </ul>
<b>Clinical Notes</b> <ul style="list-style-type: none"> <li>Consultation Note</li> <li>Discharge Summary Note</li> <li>History &amp; Physical</li> <li>Procedure Note</li> <li>Progress Note</li> </ul>	<b>Goals</b> <ul style="list-style-type: none"> <li>Patient Goals</li> <li>SDOH Goals</li> </ul>	<b>Laboratory</b> <ul style="list-style-type: none"> <li>Test</li> <li>Values/Results</li> <li>Specimen Type</li> <li>Result Status</li> </ul>		<b>Vital Signs</b> <ul style="list-style-type: none"> <li>Systolic blood pressure</li> <li>Diastolic blood pressure</li> <li>Heart Rate</li> <li>Respiratory rate</li> <li>Body temperature</li> <li>Body height</li> <li>Body weight</li> <li>Pulse oximetry</li> <li>Inhaled oxygen concentration</li> <li>BMI Percentile (2 - 20 years)</li> <li>Weight-for-length Percentile (Birth - 24 Months)</li> <li>Head Occipital-frontal Circumference Percentile (Birth - 36 Months)</li> </ul>
	<b>Health Insurance Information</b> <ul style="list-style-type: none"> <li>Coverage Status</li> <li>Coverage Type</li> <li>Relationship to Subscriber</li> <li>Member Identifier</li> <li>Subscriber Identifier</li> <li>Group Number</li> <li>Payer Identifier</li> </ul>	<b>Medications</b> <ul style="list-style-type: none"> <li>Medications</li> <li>Dose</li> <li>Dose Units of Measure</li> <li>Indication</li> <li>Fill Status</li> </ul>	<b>Problems</b> <ul style="list-style-type: none"> <li>Problems</li> <li>SDOH Problems/Health Concerns</li> <li>Date of Diagnosis</li> <li>Date of Resolution</li> </ul>	

★ New Data Classes and Elements 
 ➡ Data Element Reclassified 
 ★ ★ Name and Other Changes to Existing Data Classes/Elements

The USCDI ONC New Data Element and Class (ONDEC) Submission System supports a predictable, transparent, and collaborative process for adding new data classes and data elements to USCDI, allowing health IT users to propose new data elements and classes for future versions of USCDI.

ONC has launched a new initiative called [USCDI+](#) to support the identification and establishment of domain or program-specific datasets that will operate as extensions to the existing USCDI. USCDI+ is a service that ONC will provide to federal partners who have a need to establish, harmonize, and advance the use of interoperable datasets that extend beyond the data in the USCDI to meet agency-specific programmatic requirements. USCDI+ collaborations are underway with CDC, CMS, and the Health Resources and Services Administration focused on public health, quality, and Uniform Data System reporting.

### Standards Version Advancement Process

ONC has established the voluntary [Standards Version Advancement Process \(SVAP\)](#) to enable health IT developers to incorporate newer versions of HHS-adopted standards and implementation specifications. Using SVAP, certified health IT developers are permitted to voluntarily use versions of standards and implementation specifications approved by the National Coordinator that are more recent than those adopted in 45 CFR part 170, subpart B and referenced by the ONC 2015 Edition Certification Criteria.





## ONC Interoperability Standards Advisory (ISA)

The ISA process represents the model by which ONC coordinates the identification, assessment, and determination of recognized interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs. [The 2023 ISA Reference Edition](#) features enhanced integration with 2022 SVAP Approved Standards and includes updates related to pharmacy interoperability, human and social services, adverse event reporting, and tribal affiliation.

## Collaborations to Accelerate the HL7® FHIR® Standard

The [HL7® FHIR® standard](#) defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems. It allows healthcare information, including clinical and administrative data, to be available securely to those who have a need to access it, and to those who have the right to do so for the benefit of a patient receiving care.

HL7® FHIR® development began in 2012 in response to market needs for faster, easier, and better methods to exchange the rapidly growing amount of health data. This growth in the availability of new health data, along with the progressing “app economy,” created the need for clinicians and consumers to be able to share data in a lightweight, real-time fashion using modern internet technologies and standards. FHIR is based on internet standards widely used by industries outside of healthcare. By adopting existing standards and technologies already familiar to software developers, HL7® FHIR® significantly lowers the barriers of entry for new software developers to support healthcare needs.

In 2017, ONC spearheaded the HL7® FHIR® at Scale Taskforce (FAST), a public-private partnership with the industry, to accelerate the scalability of HL7® FHIR® across the industry. Since its inception, FAST grew larger and shifted its focus from identifying FHIR scalability challenges to proposing new solutions, including new standards development. FAST is now an official [HL7® FHIR® Accelerator](#).

CDC and ONC have collaborated with HL7® to establish the [Helios HL7® FHIR® Accelerator for Public Health](#). Helios is an alliance of government, private sector, and philanthropic partners that will help to ensure public health needs are at the forefront as the US Core HL7® FHIR® profiles evolve and roll out nationwide. The Accelerator focuses on extending and adopting existing HL7® specifications in ways that are scalable, adaptable, sustainable, and suitable for public health. Participants in Helios will help provide the resources and technical support needed for public health practitioners to develop, test, and adopt more efficient, HL7® FHIR®-based ways of accessing and exchanging data nationwide. Membership is open to federal and STLT public health agencies, private sector partners, and other groups interested in the equitable and effective use of data for the advancement of public health.

The Accelerator will assist healthcare communities and collaborative groups in the creation and adoption of high-quality HL7® FHIR® Implementation Guides or other resources to move toward the realization of health data interoperability. This program will fill the gaps to meet public health reporting needs and educate the public health community on how to best leverage FHIR® for public health.

The [Integrating the Healthcare Enterprise \(IHE\) cooperative agreement program](#), first announced in 2019, reflects ONC’s strategic aim to promote the use of the HL7® FHIR® standard and advance standardization, in support of better interoperability. Under this cooperative agreement, ONC and IHE USA have collaborated to accelerate the creation of new and updated [IHE Profiles](#) using the HL7® FHIR® standard.



An IHE profile is an implementation specification that takes at least one health IT interoperability standard, and sometimes multiple standards, and specifies how those standards should be implemented to support an interoperability use case. This allows for collaboration between users of health IT systems and an opportunity to create best practices to allow for consistent implementation of the standards across all parties.

## COORDINATION OF HEALTH IT EFFORTS

ONC is charged with formulating the federal government’s health IT strategy and promoting coordination of federal health IT policies, technology standards, and programmatic investments. ONC keeps coordination and interoperability at the forefront by soliciting feedback from various communities such as federal partners, industry, and the public.

### Health IT Advisory Committee (HITAC)

Established by the Cures Act, the HITAC is governed by the provisions of the Federal Advisory Committee Act (FACA), which sets standards for the formation and use of federal advisory committees. The HITAC provides recommendations on policies, standards, implementation specifications, and certification criteria to the National Coordinator for Health IT.

*Figure 12: HITAC Accomplishments from Jan. 18, 2018, through January 1, 2023.*



Source: [HITAC Graphic Reference](#).

### Data and Surveillance Workgroup (DSW)

The CDC's Advisory Committee to the Director, DSW, provides input on agency-wide activities related to the scope and implementation of CDC’s Data Modernization Initiative (DMI) strategy. CDC’s commitment to data modernization includes but is not limited to investments in: 1) data systems that collect, exchange, manage, or analyze data at any level of public health; 2) strategies and capabilities that support implementation of public health data system modernization; 3) policy levers, as legally appropriate, that advance the standardized collection and exchange of data to support a resilient, sustainable response-ready public health enterprise; and 4) multi-sector partnerships that accelerate the improvements in the nation’s public health data infrastructure. The DSW’s efforts assist the ACD in identifying innovative and promising modernization practices and approaches that align with the principal pillars of DMI, as well as opportunities to advance modern, harmonized data policies and practices, consistent with applicable federal law, in support of public health program activities.





multiply the impact of HHS regulations and purchasing power to improve interoperability, health equity, federal customer experience and service delivery, and competition.

### **Global Digital Health Partnership (GDHP)**

ONC represents the U.S. on the [GDHP](#) and serves as the current chair. The GDHP was founded in 2018 and now includes 36 members – 33 nations and 3 multi-national organizations. The five workstreams of the GDHP (policy environments, interoperability, clinical and consumer engagement, evidence and evaluation, and cyber security) published a [series of white papers in 2019](#) that described the state of affairs of GDHP members’ digital health. In 2020, HHS collaborated with the international community, including government officials from other countries, to create the HL7® FHIR® [International Patient Summary \(IPS\)](#) Implementation Guide (IG), an EHR minimum dataset containing essential healthcare information intended for use in unscheduled, cross-border care scenarios. As part of the Interoperability Workstream, the U.S. is currently working with a subset of GDHP countries to implement and pilot the HL7® FHIR® IPS IG with the goal that all GDHP countries will eventually be able to fully implement the FHIR IPS IG.

### **Industry-Led Actions**

While this report mainly focuses on actions taken by the federal government, industry-led contributions toward a modern and connected health IT infrastructure continue to bring innovation and competition into healthcare. Also, as the industry comes into compliance with the ONC Cures Act Final Rule, HHS anticipates a significant, industry-wide shift toward modern technology for information sharing in healthcare.

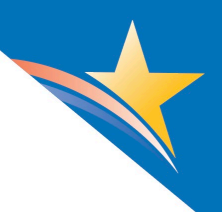
Leading technology companies in the private sector are using—or have committed to using—HL7® FHIR®-based APIs. This can help create a rich and thriving app ecosystem, building on certified health IT. The health IT and healthcare industries also continuously develop new technologies to increase computing power, propel new algorithms, develop analytic capabilities, and advance artificial intelligence (AI) and machine learning (ML) capabilities. Remote monitoring technologies such as wearables and web-enabled medical devices also continue to advance as healthcare providers and patients become more familiar with such technologies.

## **PROTECTION AND SECURITY OF EHI**

Protecting and securing EHI is a shared responsibility among healthcare providers, developers, payers, and biomedical researchers. It is critical for these health IT users to continue working together to encourage the development and implementation of technical mechanisms to strengthen the privacy and security of health information as more data are generated, accessed, and exchanged.

### **HIPAA Educational Materials**

HHS continues to create publicly available educational materials specifically designed to give HIPAA-[covered entities](#) or [business associates of covered entities](#) (HIPAA entities), insights into how to protect and secure EHI and respond to cyber-related security incidents, including updating the [HHS Security Risk Assessment Tool](#). HHS previously developed a [Top 10 Tips for Cybersecurity in Health Care](#), [Cybersecurity Checklist](#), [Cybersecurity Awareness Newsletters](#), and a [Ransomware Fact Sheet](#).



The [Security Risk Assessment Tool \(SRA Tool\)](#), developed and updated by ONC in collaboration with the HHS Office for Civil Rights, helps healthcare providers conduct and document a risk assessment in a thorough, organized fashion at their own pace by allowing healthcare providers to identify and assess the information security risks in their organizations under the HIPAA Security Rule. It is important to implement administrative, technical, and physical safeguards to provide for the confidentiality, integrity, and availability of health information. The SRA Tool helps organizations confirm these safeguards are in place and reveal areas where electronic protected health information may be at risk.

## Privacy Practices for Health Apps

Advances in technology support patients accessing their medical record information in more nimble ways. For example, patients have access to health apps that can support care management, collect data from multiple care providers, and enable patients to move information more easily to where it needs to go to best enable their care. The decision to give a health app (or third-party) access to their EHI is the patient's choice and comes with privacy and security considerations. HIPAA entities, and their business associates, that have access to a patient's EHI are required to follow [certain privacy and security requirements](#). Health apps that are accessing information on behalf of the patient are not generally regulated by HIPAA. HIPAA entities, and their business associates, should consider informing the patient of the potential risks involved the first time the patient makes the request to have their EHI transmitted to the app.

The [ONC Cures Act Final Rule](#) states that actors may establish processes to make a patient aware of the privacy policies and practices of an app. The information shared by a provider could include whether the app developer that the patient is about to authorize to receive their EHI has attested that their privacy policy practices meet certain "best practices" set by the market. The ONC Cures Act Final Rule also includes examples of what those privacy practices could be.

Most entities anticipated to exchange information pursuant to the Common Agreement are HIPAA entities, and thus will already be required to comply with HIPAA privacy and security requirements. The Common Agreement requires each non-HIPAA entity that exchanges information pursuant to the Common Agreement to protect individually identifiable information that it reasonably believes is TEFC Information in substantially the same manner as HIPAA entities protect PHI.

The Common Agreement includes provisions to support individuals accessing their information through apps that are Individual Access Services (IAS) Providers. It specifies the privacy and security requirements that a QHIN, Participant, or Sub-participant would be required to adhere to if it chooses to become an IAS Provider. IAS Providers must, among other requirements, have a written privacy and security notice; obtain express consent from individuals regarding the way their information will be accessed, exchanged, used, or disclosed; and provide individuals with the right to obtain an export of their data in a computable format. In some ways, IAS providers will have to meet additional privacy and security requirements than might be required under HIPAA including providing individuals with the right to delete their data and encrypting all Individually Identifiable information.

As technical capabilities for health information access, exchange, and use continue to expand, the federal government remains committed to supporting the privacy and security of EHI.





## Telehealth Remote Patient Monitoring Ecosystem Practice Guide

The National Cybersecurity Center of Excellence (NCCoE) at the National Institute of Standards and Technology (NIST) brings together experts from industry, government, and academia to solve complex, real-world cybersecurity challenges. Using standards and best practices, the NCCoE and its collaborating partners demonstrate how to apply secure technologies to accelerate the adoption of cybersecurity and improve the security posture of businesses.

After a public comment period, NIST's NCCoE published in February 2022 the [NIST Cybersecurity Practice Guide, SP 1800-30](#) with the goal to provide a practical solution for securing the telehealth remote patient monitoring (RPM) ecosystem.<sup>27</sup> This publicly available NIST Cybersecurity Practice Guide offered a detailed implementation guide of the practical steps to implement a cybersecurity reference design that addresses this challenge. This effort supported enhancing the delivery and experience of care with health IT to expand access and connect patients to care in a secure manner.

## MODERNIZATION OF PUBLIC HEALTH DATA SYSTEMS

The COVID-19 pandemic exposed outdated public health data systems and a lack of interoperability between national, state, local, and tribal health departments, and epidemiology centers in the United States. The pandemic also further exposed preventable health disparities around access and administration of healthcare.<sup>28</sup> With foundational activities launched to address these issues, HHS remains committed to modernizing public health data systems.

### Modernize Public Health Data Systems

The [CDC Data Modernization Initiative \(DMI\)](#) marks the first comprehensive strategy to modernize data, technology, and workforce capabilities to support public health surveillance, research, and ultimately, decision-making.

In May 2021, the HITAC established the Public Health Data Systems Task Force to inform HHS's advancement for Section 3 of the [Executive Order](#) on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats. The [HITAC recommendations](#) identified policy and technical gaps associated with the effectiveness, interoperability, and connectivity of information systems relevant to public health. This included a focus on surveillance systems, infrastructure improvements, health equity, clinical engagement, long-term service and support systems, research, and innovation, and educating and empowering individuals. These recommendations are informing HHS actions to modernize public health data systems.

### North Star Architecture

[The North Star Architecture](#), a joint effort between CDC and ONC, is a core component of CDC's approach for making public health systems work better. A primary goal of the efforts is to make available flexible, interoperable, and secure digital tools that can be used by CDC and public health partners at STLT levels. These digital tools are intended to provide different levels of support, from guidance to complete solutions, to meet STLTs and CDC programs where they are today and help support them in their modernization journey of getting to where they want to be. Together, the tools will form the "blueprint" for a sustainable, response-ready public health ecosystem.



## Helios Initiative

[Helios](#) is an initiative launched by HL7®, supported by CDC and ONC, to advance public health data exchange using the HL7® FHIR® standard. This alliance of government, private sector, and philanthropic partners is committed to the equitable and effective use of data for the advancement of public health. Members will help ensure data modernization efforts in public health incorporate, as appropriate, market-based solutions that incentivize participation and are compatible with nationwide interoperability priorities.

## Nationwide Electronic Case Reporting (eCR) Expansion

Many state public health agencies rely on slow reporting processes, such as faxes and phone calls. CDC's eCR automates case reporting allowing secure health data to flow directly from the healthcare provider's EHR system to state public health agencies through a standards-based, shared, and interoperable infrastructure. EHR industry partners can either build eCR capability into their EHR products or use the eCR Now application created by CDC with the HL7® FHIR® application programming interface (API) version R4 enabling state public health agencies to receive eCR data in near real-time. This innovative health IT solution helps alleviate previous burdensome administrative reporting processes, giving providers more time to spend with their patients delivering care.<sup>29</sup> Beginning in 2022, an eCR measure is required by the CMS Promoting Interoperability Program for eligible hospitals and CAHs.<sup>30</sup> HHS continues to leverage these technological advancements for eCR to support government mitigation, response, and recovery efforts and to expand the availability of supportive technologies across health IT systems.

## ONC Public Health Informatics and Technology (PHIT) Workforce Development Program

Using funding provided by the American Rescue Plan Act of 2021, ONC announced an \$80 million Public Health Informatics & Technology ([PHIT Workforce Development Program](#)). The PHIT Workforce Development Program aims to implement or expand training, certification, and degree programs in public health informatics and data science at minority serving institutions (MSIs) and other colleges and universities.

The 10 awardees, comprising Historically Black Colleges and Universities (HBCUs), Hispanic Serving Institutions (HSIs), Asian American and Native American Pacific Islander-Serving Institutions (AANAPISIs), and other institutions of higher education, are collectively training more than 4,000 individuals over a four-year period through an interdisciplinary approach in public health informatics. The consortia are ensuring these trainings, certifications, and degree programs are sustainable to create a continuous pipeline of diverse public health informatics and technology professionals.

## The Strengthening the Technical Advancement and Readiness of Public Health via Health Information Exchange Program (The STAR HIE Program)

In September 2020, ONC awarded five cooperative agreements under the [STAR HIE Program](#). The program built innovative health information exchange services that benefited public health agencies and improved the availability of health information exchange services to support communities disproportionately impacted by the COVID-19 pandemic. In January 2021, ONC awarded 17 additional HIE cooperative agreements to support efforts to increase data sharing between jurisdictional Immunization Information Systems (IIS) and HIEs. The STAR HIE Program supported public health agencies' abilities to advance data-driven prevention of, response to, and recovery from public health emergencies, such as COVID-19.



### **The Situation Awareness for Novel Epidemic Response (SANER) Project**

In March 2020, the [SANER Project](#) launched in response to concerns from public health departments, HIEs supporting public health, and from public health officials at the regional, state, and federal level in the United States. The goals include developing a specification that will support communication of essential situation awareness data for consumption by public health, testing the ability of systems to use this specification, and piloting test systems implementing the specification in real-world settings.

### **COVID-19 Immunization Data Exchange, Advancement and Sharing (IDEAS) Program**

The [ONC IDEAS Program](#) focuses on ensuring that public health agencies and healthcare providers are better able to access, share, and use COVID-19 immunization administration data. This program established a formal collaboration with Association of State and Territorial Health Officials (ASTHO) to strengthen and expand the ability of IISs to share data with HIEs. Enabling the secure exchange of immunization data between state IISs and HIEs benefits patients, providers administering vaccines, and public health agencies overseeing the health of their local populations. When HIEs have access to state or local immunization data through IISs, both public health agencies and clinicians will be equipped to administer immunizations more effectively to at-risk patients and manage adverse reactions or outcomes as more of the U.S. population becomes vaccinated.

### **Support of Health Equity and Comprehensive Health and Care Needs**

In alignment with [Executive Order 13985](#): Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, HHS is “committed to pursuing a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.”

ONC is committed to identifying and addressing gaps in health equity by supporting the [HHS Equity Action Plan](#) and capturing data central to understanding equity considerations. Comprehensive healthcare includes not only physical health, but also mental health, substance use/misuse, and SDOH. Long-term and post-acute care, hospice, behavioral health, and home and community-based services providers often deliver care to vulnerable individuals, including patients with multiple chronic physical and mental health conditions. Improving timely EHI capture via certified health IT and interoperable data exchange across all providers will enable more equitable healthcare delivery.

### **Embrace Health Equity by Design**

ONC is focused on including health equity as a key feature during the design stage of a policy, program, or project. This concept of “[Health Equity by Design](#)” involves identifying and addressing gaps in health equity during the development and implementation of technologies so that the technology itself aids, rather than exacerbates, health disparities.

### **Artificial Intelligence and Machine Learning**

The NIH [Common Fund’s Bridge to Artificial Intelligence \(Bridge2AI\) program](#) focuses on propelling biomedical research forward as it plans for the widespread adoption of AI. The goal of Bridge2AI is to develop guidance that generates AI-ready data that incorporates ethical considerations, requirements for interdisciplinary teams and workforce development, and the need for common standards. NIH also strives to reduce inequities in healthcare, increase diversity among AI researchers, and close gaps in health-related datasets. To better engage underrepresented communities, the NIH Artificial Intelligence/Machine





Learning Consortium to Advance Health Equity and Researcher Diversity ([AIM-AHEAD](#)) program builds regional, multi-disciplinary partnerships.

In March 2021, the Agency for Healthcare Research and Quality (AHRQ) Evidence-Based Practice Centers submitted a Request for Information ([RFI on the Use of Clinical Algorithms](#)). The results of the RFI informed the AHRQ protocol for an evidence review on the Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare Report published in January 2022. The evidence review is forthcoming.<sup>31</sup>

### **Substance Abuse and Mental Health Services Administration (SAMHSA) Grants**

SAMHSA has expanded the [Certified Community Behavioral Health Clinics \(CCBHC\) grant program](#), which requires grantees to use health IT systems to facilitate care coordination. These grants can promote modernizing the health IT infrastructure and improving patients' experience. Furthermore, grantees are required to make available specialized services for purposes of outpatient mental and substance use disorder treatment, through referral or formal arrangement with other providers or, where necessary and appropriate, through use of telehealth services.

In May 2021, [HHS announced \\$3 billion in American Rescue Plan Act of 2021 funding to support SAMHSA Block Grants](#) to address addiction and the ongoing mental health crisis exacerbated by the COVID-19 pandemic.

### **CMS State Health Official Letter to Address SDOH**

In January 2021, CMS issued a [letter to state health officials](#) describing opportunities under Medicaid and the Children's Health Insurance Program (CHIP) to better address SDOH and to support states with designing programs, benefits, and services that can more effectively improve population health, reduce disability, and lower overall health care costs in the Medicaid and CHIP programs by addressing SDOH.

The letter also included information on available Medicaid resources to support data integration and data sharing to assist state health systems in identifying individuals with SDOH needs and linking them to appropriate medical and social support services. Additionally, the letter encouraged states to participate in the HL7 accelerator [Gravity Project](#) as appropriate. The Gravity Project focuses on identifying coded data elements and associated value sets to represent SDOH screening, diagnosis, planning, and interventions in health IT systems.

### **Opioid Prescribing Support Implementation Guide**

As part of a Clinical Quality Framework Initiative, a public-private partnership—sponsored by ONC and CMS—created an [Opioid Prescribing Support Implementation Guide](#) to identify, develop, and harmonize standards for clinical decision support and electronic clinical quality measurement. This implementation guide provided resources and discussion in support of applying the [CDC Opioid Prescribing Guideline](#).

### **Leveraging Prescription Drug Monitoring Programs (PDMPs) and Health IT to Address Substance Use Disorder and Opioid Misuse (LPASO)**

ONC engages in collaborative work to understand the role of health IT in addressing the opioid crisis, including the opportunities created by state PDMP systems. ONC established the [LPASO](#) Project to examine policy and technical efforts related to PDMPs, health IT, and the opioid epidemic. This effort examined how states, the District of Columbia, and U.S. territories use health IT to expand the



functionality of PDMPs to address the opioid overdose epidemic and analyze health IT policy and technical approaches. More recently, [LPASO 2.0](#) partnered with the National Governors Association (NGA) to convene a virtual meeting with state leaders to focus on promising PDMP practices and create a [toolkit](#) to support the successful implementation and use of health IT and PDMPs.

### **Leading Edge Acceleration Projects (LEAP) in Health IT**

Since 2018, ONC has offered new [LEAP in Health IT](#) funding opportunities to address well-documented and fast-emerging challenges that inhibit the development, use, and advancement of health IT. LEAP in Health IT projects are expected to further a new generation of health IT development and inform the innovative implementation and refinement of standards, methods, and techniques for overcoming major barriers and challenges as they are identified.

Currently, there are eight active LEAP in Health IT awards. In 2021, the University of Texas at Austin was awarded the LEAP project “Referral Management to Address SDOH Aligned with Clinical Care.” The goal is to create an API-enabled Social and Health Information Platform using the HL7® FHIR® standard to integrate a closed loop social services referral system. The system will be accessible to the EHRs used by Federally Qualified Health Centers (FQHCs) to leverage SDOH data.

## **ADVANCEMENT OF HEALTH IT FOR RESEARCH AND DATA ANALYTICS**

Widespread adoption of certified health IT and the capture of large volumes of electronic health data provide a tremendous opportunity for population health, research, and innovation. Certified health IT serves as a foundation and data engine on which to build advanced data analytics to support individual and population health as well as improve the science and delivery of healthcare. However, challenges include assurance of data quality and consistency, establishment of governance structures and policies that allow for access to data, limited development of research tools and services, variations in implementation across the technical architecture, and the varying needs of individuals and organizations that contribute to and use data within the infrastructure.<sup>32</sup>

### **Synthetic Health Data Generation to Accelerate Patient-Centered Outcomes Research (PCOR)**

HHS led multiple projects that inform policy, standards, and services specific to the adoption and implementation of [patient-centered outcomes research \(PCOR\)](#) data infrastructure. One of ONC’s [current PCOR projects](#) focuses on enhancing the ability of software to produce high-quality synthetic data for opioid, pediatric, and complex care use cases. [Synthea](#), a synthetic health data engine, uses publicly available data to generate synthetic health records that can be exported in multiple standardized formats. Synthetic data sets are compatible with HL7® FHIR® and Consolidated-Clinical Document Architecture.

### **Federal Agencies Encourage HL7® FHIR® Standard to Exchange Research Data**

The use of HL7® FHIR® fosters increased data sharing among patients, healthcare providers, payers, and researchers. Some federal agencies, such as [AHRQ](#) and [NIH](#), are encouraging researchers to explore the use of the HL7® FHIR® standard to capture, integrate, and exchange healthcare data for research purposes and to enhance capabilities to share research data.



## **National Health IT Priorities for Research: A Policy and Development Agenda**

In 2020, ONC published the [National Health IT Priorities for Research: A Policy and Development Agenda](#). This agenda has guided the realization of a health information ecosystem in which both the health IT infrastructure and data it supports advance scientific discovery. Furthermore, the use of USCDI will enable researchers to leverage structured clinical data for research and enhance the ability to aggregate research data sets, and enable discovery. In July 2020, NIH issued a [notice](#) encouraging NIH-supported clinical programs and researchers to adopt and use USCDI v1 to enable greater interoperable exchange of health information for clinical care and research.

## **FDA Technology Modernization Action Plan (TMAP)**

In September 2019, the FDA announced its [TMAP](#), which aims to address the barriers that impede the translation of scientific and biomedical advances into real-world solutions to improve public health. The plan has three elements:

1. Modernization of FDA's technical infrastructure;
2. Enhancement of FDA's capabilities to develop technology products to support its regulatory mission; and
3. Communication and collaboration with communities to drive technological and interoperable progress across the system and deliver value to consumers and patients.

The TMAP has provided a technological foundation for the development of FDA's ongoing strategy for the stewardship, security, quality control, analysis, and real-time use of data that will accelerate the path to better therapeutic and diagnostic options for patients and providers. The TMAP has focused on near-term modernization in technologies, including real-time dashboards, blockchain, and AI.

FDA also collaborated with developers to conduct a FedRAMP security assessment for a new genomics platform. Lessons learned from this partnership will inform FDA's efforts to support regulatory efficiency and facilitate cloud adoption without compromising security or privacy.



# Recommendations

HHS, in collaboration with federal partners, will continue progress on actions that advance the [2020-2025 Federal Health IT Strategic Plan](#). These efforts aim to improve the health and well-being of individuals and communities using technology and health information that is accessible when and where it matters most.

HHS thanks Congress for the vision, passage of, and continued commitment to the Cures Act. HHS recommends continued and full Congressional support for the implementation of the health IT provisions in the Cures Act. In addition, the following are overarching recommendations to Congress to improve the use of health IT to promote health and wellness; enhance the delivery and experience of care; and build a secure, data-driven ecosystem to accelerate research and innovation by supporting ONC efforts to:

- Support “health equity by design” to include equitable access to information and communications technology, and improve health outcomes by building equity into the design of health IT.
- Coordinate with the CDC and other HHS agencies so that federal and STLT, public health data systems are modernized using health IT standards that enable the collection, access, exchange, use, and reporting of public health data to prevent and mitigate public health threats.
- Promote the appropriate sharing of information by educating patients and the care community about [information blocking policy and regulations](#), track information blocking complaints, and coordinate with the HHS OIG and other HHS components on information blocking enforcement.
- Implement [TEFCA](#) to create a nationwide policy and technical infrastructure approach to better enable information sharing across health information networks.
- Advance standards to support health information sharing across all care settings, including APIs and the USCDI, via certified health IT systems.
- Coordinate with federal agencies to ensure ONC-adopted standards support EHI access, exchange, and use across federal programs and health IT systems.



# Appendix A – 2020-2025 Federal Health IT Strategic Plan

The [2020-2025 Federal Health IT Strategic Plan](#) includes four goals, each of which includes specific objectives and strategies. Federal organizations' actions to implement the Strategic Plan are outcomes-driven, focusing on meeting the EHI needs of individuals, populations, caregivers, healthcare providers, public health professionals, payers, researchers, developers, and innovators. The Strategic Plan guides federal health IT actions and serves as a catalyst for activities in the private sector.

<b>GOAL 1</b> <b>Promote Health and Wellness</b> <b>Objective 1a:</b> Improve individual access to usable health information <b>Objective 1b:</b> Advance healthy and safe practices through health IT <b>Objective 1c:</b> Integrate health and human services information	<b>GOAL 4</b> <b>Connect Healthcare with Health Data</b> <b>Objective 4a:</b> Advance the development and use of health IT capabilities <b>Objective 4b:</b> Establish expectations for data sharing <b>Objective 4c:</b> Enhance technology and communications infrastructure <b>Objective 4d:</b> Promote secure health information practices that protect individual privacy
<b>GOAL 2</b> <b>Enhance the Delivery and Experience of Care</b> <b>Objective 2a:</b> Leverage health IT to improve clinical practice and promote safe, high-quality care <b>Objective 2b:</b> Use health IT to expand access and connect patients to care <b>Objective 2c:</b> Foster competition, transparency, and affordability in healthcare <b>Objective 2d:</b> Reduce regulatory and administrative burden on providers <b>Objective 2e:</b> Enable efficient management of health IT resources and a nationwide workforce confidently using health IT	
<b>GOAL 3</b> <b>Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation</b> <b>Objective 3a:</b> Advance individual- and population-level transfer of health data <b>Objective 3b:</b> Support research and analysis using health IT and data at the individual and population levels	



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