



# Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2023

**FEBRUARY 8, 2024**

**PREDECISIONAL DRAFT**





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## FOREWORD

We are pleased to present the annual report of the HITAC for fiscal year 2023 (FY23).

This report describes the work undertaken by the HITAC during its sixth year. The HITAC was formed by the Cures Act and is governed by the Federal Advisory Committee Act. The HITAC is a federal advisory committee composed of members representing hospitals and health systems, healthcare providers, health information exchanges, insurers, health IT developers, universities, and federal agencies, as well as patients and consumers. Working together, HITAC members make recommendations about policies, standards, implementation specifications, and certification criteria to the National Coordinator for Health Information Technology (National Coordinator) within the Department of Health and Human Services (HHS).

In this report, the HITAC evaluates the health IT infrastructure landscape of the United States for gaps, opportunities, and recommendations. The HITAC focused its evaluation on five target areas: design and use of technologies that advance health equity, use of technologies that support public health, interoperability, privacy and security, and patient access to information. In FY23, the HITAC made recommendations in support of the Office of the National Coordinator for Health IT (ONC)'s Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule. The HITAC also made recommendations on the United States Core Data for Interoperability (USCDI) Draft Version 4 (v4) and completed work on the needs of public health data systems. Finally, the HITAC began deliberating on the topic of pharmacy interoperability and emerging therapeutics. Several areas for potential future HITAC work surfaced during the HITAC meetings in FY23 that may result in activity in fiscal year 2024 (FY24) and beyond.

We wish to acknowledge and appreciate all the hard work done by committee members and additional members of the public serving on the HITAC subcommittees, as well as by committee members participating in the deliberations of the committee as a whole. In addition, we thank the staff of ONC and the other federal agencies that support the HITAC.

It has been our privilege to serve as co-chairs for the HITAC, Aaron since January 2021 and Medell beginning in January 2023. The commitment and diverse expertise of the HITAC members have brought both energy and insight to this evaluation of the U.S. health IT infrastructure. The HITAC expects another busy year as it continues to identify and promote the use of better information and technology to improve care delivery and the health and well-being of everyone in the United States.

Medell Briggs-Malonson and Aaron Miri  
Co-Chairs, Health Information Technology Advisory Committee during FY23\*

\* Sarah DeSilvey began her term as a HITAC co-chair on January 1, 2024, replacing Aaron Miri. However, this foreword was co-authored by the co-chairs who led the HITAC during its FY23 activities.



## INTRODUCTION

The 21st Century Cures Act (Cures Act) requires the HITAC to develop an annual report to be submitted to the Secretary of HHS and to Congress each fiscal year. This report complies with that directive by describing the landscape of health information technology (health IT) infrastructure across target areas, analyzing infrastructure gaps, and offering recommendations for future HITAC activities. The report also reviews FY23 HITAC activities.

## HEALTH IT INFRASTRUCTURE LANDSCAPE

The Cures Act identifies several target areas within which the HITAC should focus its activities, including the design and use of technologies that advance health equity, the use of technologies that support public health, interoperability, privacy and security, and patient access to information. These five target areas are used to organize this report.

### Target Area: Design and Use of Technologies that Advance Health Equity



#### Illustrative Story of What the Recommended HITAC Activities Will Enable in the Future

An older adult with diabetes has not had an eye exam for several years. The patient is experiencing worsening vision and needs to see a specialist. This patient lives in a rural area without broadband Internet access and lacks reliable transportation to the practice's office. However, the practice offers telehealth appointments through a secure platform that provides screen-reading and voice-to-text technology. The platform has also integrated standardized social drivers of health (SDOH) data elements. After gaining access to broadband Internet via a public-private partnership and with help from the practice's office administrator and some digital literacy education, the patient is able to meet with the specialist online.

Through the online platform and the use of smart-phone-enabled retinal scanning technologies that use AI to analyze retinal images taken through the smart-phone camera, the specialist is able to accurately assess the severity of the patient's disease and recommend a treatment plan that minimizes patient burden and limits the need to travel long distances for an in-person visit. This not only improves the patient's ability to adhere to screening and consultations that could preserve their vision, but it also decreases the burden on the patient's family and government-funded transportation services that would have been necessary to transport the patient to the specialist's office.

Health equity is achieved when all people have a fair and just opportunity to attain their highest level of health. The intentional design and implementation of health IT infrastructures, policies, and practices are needed to identify and mitigate clinical and social inequities that contribute to unjust variations in health between populations. While challenges remain in health IT infrastructure to standardize and collect health equity and SDOH data, federal agencies, states, and private sector initiatives are moving the needle to provide more guidance for equitable data collection. Standards efforts continue to improve the interoperability of data about social drivers of health, also known as social determinants of health data. The HITAC has adopted the term social "drivers" of health instead of "determinants". The term "drivers" demonstrates that health-related social needs are dynamic and can be influenced to improve overall health and social well-being, while the term "determinants" inaccurately implies that these social contributors are fixed and immutable. Artificial intelligence (AI) tools have the potential to improve healthcare for patients



but also to exacerbate existing care inequities if they contain biases or use biased data. As technology continues to advance, further requirements and initiatives are needed to reduce the digital divide and increase access to and accessibility of telehealth services to ensure health equity.

## Target Area: Use of Technologies that Support Public Health



### Illustrative Story of What the Recommended HITAC Activities Will Enable in the Future

A town experiences a sudden surge in cases of gastrointestinal illness clustered in an area where residents live in overcrowded housing and have limited access to healthcare. The local and state public health departments had implemented a data exchange method leveraging the Trusted Exchange Framework and Common Agreement (TEFCA) that allows them to access and exchange data with hospitals and other healthcare providers in real time. After analyzing clinical and laboratory data obtained through syndromic surveillance, electronic laboratory reporting, electronic case reporting, and other systems as well as collaboration with other public health agencies, the local department is able to utilize TEFCA to access additional medical information and act to control the disease outbreak.

After conducting tests of samples from the municipal water supply serving the cluster of homes affected by the outbreak, they identify the contaminant and issue a “boil water” advisory. As a result of the local public health department's fast response, the outbreak is quickly contained. They also review transportation insecurity data to offer transportation to local care centers to those affected who need rehydration therapy.

The COVID-19 pandemic has highlighted the crucial role of health IT in responding to public health emergencies while also revealing areas that need improvement. Public health data systems are essential for monitoring and addressing public health issues, as well as collecting, managing, analyzing, and disseminating data on diseases, injuries, and health outcomes to guide public health policy and decision-making. Unfortunately, the nation's public health data systems are outdated, fragmented, and chronically underfunded, resulting in delayed detection and response. These systems need to be modernized to support increased interoperability and standards for epidemiological and syndromic surveillance.

## Target Area: Interoperability



### Illustrative Story of What the Recommended HITAC Activities Will Enable in the Future

A skilled nursing facility (SNF) recently implemented an electronic health record (EHR) system. The new EHR includes interoperability functionality that allows the SNF to electronically send and receive patient health information with a nearby hospital for the first time. As a result, the SNF is able to see more patient information from the hospital records at the point of care and share updated patient records with the hospital, which include data from medical devices used to monitor chronic diseases, such as diabetes, high blood pressure, and congestive heart failure. The seamless data sharing improves care coordination during transitions to and from the hospital and decreases the administrative burden on the patients and their families, who had previously been responsible for ensuring that the most up-to-date and comprehensive data was shared with providers in both facilities. Through the EHR developer, the SNF administrators also learn about the TEFCA and create a plan to participate so they can send and receive more health information including benefits determination.



The health information ecosystem continues to strive for improved interoperability. National and regional health information networks are growing and expanding their supported use cases including the TEFCA. However, interoperability remains fragmented across the care continuum, pointing to the need for better data linking, increased use of standards by laboratories and pharmacies, and continued efforts to prevent information blocking. In particular, long-term and post-acute care (LTPAC) providers' systems require more support to enable bidirectional exchange with other healthcare providers that have already adopted certified Health IT Modules.

## Target Area: Privacy and Security



### Illustrative Story of What the Recommended HITAC Activities Will Enable in the Future

An adult patient who has received behavioral health care from a health system is interested in learning more about how the health system uses their data. The health system partners with a non-profit organization to provide free training to patients on new data segmentation capabilities available to patients to further limit which data may be shared and how their de-identified data is used. Based on this training, the patient uses an open-source consent management platform to review their EHR and to restrict sharing their behavioral health treatment data with certain other healthcare providers. This is possible because a collaboration between providers, health IT developers, and government agencies has defined use cases for sensitive health data, established the needed terminology value sets, and implemented foundational infrastructure to support the exchange of granular consent directives.

Through the patient portal, they are able to receive monthly audit statements listing who has accessed their data that month and for what purpose. They also learn about a new annual transparency report that outlines how the health system uses de-identified data. The report provides the patient with a clear understanding of who has received de-identified data from the health system and for what purposes the data was shared. Over time, the patient is able to develop a sense of trust that the healthcare system is honoring their privacy choices and becomes more comfortable with sharing intimate information with their mental health care providers that enables the providers to help them heal and recover from past trauma.

As interoperability and access to patient health information increase, the privacy and security of health data continue to be of concern. Robust privacy and security practices are important considerations in advancing and maintaining trust in interoperability. Patients, business associates, and covered entities continue to require clarity about how to ensure the privacy and security of personal health data, both subject to and not subject to the Health Insurance Portability and Accountability Act (HIPAA), as well as ways in which this data can be used. Sensitive health data increasingly exist in digital environments and are governed by a patchwork of inconsistent privacy laws. Today, health IT systems cannot reliably segment and label discrete pieces of data, which hinders their ability to exchange sensitive health data that is required to provide high-quality care. In addition, patients have limited transparency into how their identified and de-identified health data are shared and disclosed.



## Target Area: Patient Access to Information



### Illustrative Story of What the Recommended HITAC Activities Will Enable in the Future

An endocrinologist is looking for health apps for diabetes with proven medical outcomes as well as strong privacy and security features. She turns to a new healthcare industry-sponsored website that provides guidance for clinicians on medically vetted health apps that are certified to relevant privacy and security criteria. The doctor links several of these apps to the practice's patient portal as resources. The doctor can then direct her diabetic patients to the practice's patient portal where the patients can choose from the vetted apps. For instance, one of the apps allows the endocrinologist to see data collected by the patient at home directly in the patient's EHR.

Sharing health information with patients in a timely manner supports patients' autonomy in their healthcare while improving patient-provider communication. As more patients use mobile health apps, concerns have arisen regarding whether they are reliable, effective, and designed to support all patient populations, particularly under-resourced populations. Patients often still face barriers to accessing, using, and correcting their health information from multiple providers. Patient-generated health data (PGHD) can be challenging to transfer into EHRs and time-consuming for healthcare providers and patients to access, requiring special effort. The healthcare industry and the federal government have taken several steps to improve price/cost and coverage transparency; however, challenges remain.



## Federal Activities across the Target Areas

In FY23, the federal government advanced several initiatives to improve health IT. ONC continued its implementation of the 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). In January 2024, ONC published its HTI-1 final rule to implement provisions of the Cures Act and make updates to the ONC Health IT Certification Program with new and updated standards, implementation specifications, and certification criteria.

In December 2023, HHS announced the designation of the first five QHINs: eHealth Exchange, Epic Nexus, Health Gorilla, Konza, and MedAllies, and data exchange began over the TEFCA network. The TEFCA Recognized Coordinating Entity (RCE), The Sequoia Project, continued to release additional resources to operationalize the TEFCA, including standard operating procedures (SOPs) and the TEFCA Facilitated FHIR<sup>®</sup> Implementation Guide (IG). The SOPs include specific policies and procedures to further guide Qualified Health Information Networks (QHINs) and identify, where applicable, necessary technical implementation requirements. In August 2023, ONC awarded the Sequoia Project a new five-year contract to continue serving as the RCE.

In July 2023, ONC published the final USCDI v4 which added 20 new data elements and one new data class that focus on patient care and patient access while promoting equity, supporting communities, reducing disparities, and supporting public health data interoperability. ONC also continued advancing the USCDI+ initiative that supports the identification and establishment of domain- or program-specific datasets for federal partners that will operate as extensions to the existing USCDI. In May 2023, ONC published the first draft of the USCDI+ data element list for quality measurement to serve as a baseline dataset to support electronically reported quality measures. In December 2023, ONC unveiled a new platform for organizing the available USCDI+ datasets and released for comment the USCDI+ Public Health data sets for case reporting and laboratory data exchange.





## HEALTH IT INFRASTRUCTURE GAPS, OPPORTUNITIES, AND RECOMMENDATIONS

The Cures Act requires an analysis identifying existing gaps in policies and resources for achieving the ONC objectives and benchmarks (see Appendix) and furthering interoperability throughout the health IT infrastructure, as well as recommendations for addressing the gaps identified. The HITAC has focused on key gaps and opportunities for the health IT industry and has recommended a set of related HITAC activities for future consideration.

The following table summarizes the HITAC’s assessment. Within each target area, topics are grouped by the timeliness of the opportunity to be addressed by the HITAC. An immediate opportunity correlates to planned topics for the HITAC within the next one to two years, i.e., calendar years 2024-25, while longer-term opportunities are anticipated to begin in three or more years, i.e., calendar year 2026 or later.

Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
<b>Target Area: Design and Use of Technologies that Advance Health Equity</b>			
<b>Immediate Opportunities</b>			
Artificial Intelligence — Algorithmic Bias and Transparency*	<ul style="list-style-type: none"> <li>AI holds significant promise in solving healthcare challenges, yet research and regulations are necessary to ensure that bias and harm are not implemented in the design and use of new technologies.</li> <li>Decision support interventions (DSIs) and predictive models lack the patient and caregiver perspective.</li> </ul>	<ul style="list-style-type: none"> <li>Assist in the implementation of existing and upcoming federal policies to address algorithmic bias, improve transparency, and support coordination across public and private initiatives.</li> <li>Explore how patients and caregivers could be more involved in determining what constitutes “fair, appropriate, valid, effective, and safe” (FAVES) DSIs. In particular, it would be helpful to gain more consensus across the health IT industry and with patients and caregivers about the definitions of fairness and appropriateness and how to measure them for predictive DSI.</li> </ul>	<ol style="list-style-type: none"> <li>In collaboration with relevant HHS agencies, support the development of guidance to assist providers, certified health IT developers, and other health IT developers with the implementation of the HTI-1 final rule’s algorithm bias policies, including their evaluation of FAVES and the implications for specific patient populations.</li> <li>In collaboration with relevant HHS agencies and including the patient and caregiver perspectives, hold a listening session focused on:                         <ol style="list-style-type: none"> <li>Understanding the current landscape of public and private AI initiatives.</li> <li>How various organizations are defining FAVES standards with an emphasis on fairness and appropriateness and how to standardize measuring them in healthcare settings for predictive DSIs.</li> </ol> </li> </ol>
Reducing the Digital Divide — General	Further requirements and initiatives are needed to reduce the digital divide, including encouraging health equity to be a core design feature and component in healthcare.	Enhance patients’ ability to engage with healthcare providers through technology, while reducing inequities and risks for under-resourced populations.	Encourage ONC to work with other HHS agencies and standards developers to adopt standardized SDOH data elements about a patient’s internet access status, digital literacy status, and health literacy status.
Reducing the Digital Divide — Increasing Access to and Accessibility of Telehealth Services	Telehealth continues to bridge access gaps but still poses risks of exacerbating disparities.	Support the adoption of security and accessibility standards by telehealth providers.	Explore the benefits and challenges of encouraging the adoption of security and accessibility standards by telehealth providers.



Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
<b>Longer-Term Opportunities</b>			
Missing Health IT Infrastructure for Health Equity and SDOH Data	The collection of health equity and SDOH data remains inconsistent due to a lack of standardization, the infrequency of the recording of this data, and the lack of adoption of IT tools by CBOs, public health organizations, and social service providers.	<ul style="list-style-type: none"> <li>Identify gaps in standards to support the capture and exchange of missing SDOH data elements.</li> <li>Support appropriate implementation of health IT by CBOs, public health organizations, and social service providers, and enable private and secure exchange and use of SDOH data.</li> </ul>	<ol style="list-style-type: none"> <li>In collaboration with relevant HHS agencies, hold a listening session to identify gaps in SDOH standards, including those that have been developed and are under development.</li> <li>Explore the development of a framework to support the adoption, implementation, and use of health IT by CBOs, public health organizations, and social service providers. The framework should identify strategies to support the private and secure exchange and use of SDOH data, including pilot demonstrations.</li> </ol>
<b>Target Area: Use of Technologies that Support Public Health</b>			
<b>Immediate Opportunities</b>			
Gaps in Infrastructure and Standards to Support Data Sharing for Public Health Purposes	There is a need for infrastructure to support data sharing that promotes coordination and standardization across different systems and data sources.	Leverage the existing infrastructure to simplify the bi-directional sharing of data between public health authorities and healthcare providers. For example, increased data exchange would aid in the real-time identification of emerging public health threats.	<ol style="list-style-type: none"> <li>Hold a listening session to identify elements of a framework that supports increased interoperability and standards for epidemiological and syndromic surveillance.</li> <li>Invite the TEFCA RCE and state, territorial, local, and tribal (STLT) organizations to provide periodic updates to the HITAC and to seek input on the identification and adoption of a public health use case.</li> </ol>
<b>Target Area: Interoperability</b>			
<b>Immediate Opportunities</b>			
Supporting Interoperability Standards – Laboratories and Pharmacies	<ul style="list-style-type: none"> <li>The lack of consistent use of standards by laboratories and pharmacies creates a barrier to interoperability.</li> <li>There is a lack of infrastructure to support the connectivity of pharmacy data with the broader health IT ecosystem.</li> </ul>	<ul style="list-style-type: none"> <li>Explore requirements for reference laboratories to adopt USCDI data classes and elements.</li> <li>Help pharmacies leverage the TEFCA for treatment purposes.</li> <li>Explore requirements for pharmacies to provide NDC and RxNorm codes.</li> </ul>	<ol style="list-style-type: none"> <li>Explore what steps the Centers for Medicare &amp; Medicaid Services (CMS) may be taking to incentivize or require laboratory and pharmacy interoperability.</li> <li>Please refer to <a href="#">HITAC's report to the National Coordinator on Pharmacy Interoperability and Emerging Therapeutics</a>.</li> <li>Please refer to Recommendation 38 in the <a href="#">HITAC's report to the National Coordinator on Public Health Data Systems</a>.</li> </ol>
Information Blocking — Infeasibility Exception	With regard to the information blocking rules, an actor's ability to comply with requests for access, exchange, or use of electronic health information (EHI) is sometimes limited.	Explore the implications of extending the time allowed for compliance with the Infeasibility Exception of the information blocking rules, if only by a few days.	Hold a listening session to hear from affected actors about the barriers to compliance within the timeframes in the information blocking rules and potential solutions that would enhance compliance while also addressing the concerns of the actors and other affected parties.
Information Blocking — Registries	There is some confusion in the health IT industry about if and when organizations that operate disease or patient registries are considered actors under the information blocking rules with respect to providing access to registry data.	Assist in the implementation of existing and upcoming federal policies that could affect access to registry data.	Support the development of guidance about if and when a disease or patient registry would be considered an actor subject to the information blocking rules with respect to providing access to registry data.



Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Standards to Support Data Linking and Patient Matching*	<ul style="list-style-type: none"> <li>The lack of standardized health data linking has resulted in a disparity of interoperability across systems and states.</li> <li>Patient matching when sharing data needs to be improved, especially for vulnerable populations.</li> </ul>	<ul style="list-style-type: none"> <li>Explore possibilities for a national strategy on data linkage, especially across QHINs.</li> <li>Efforts addressing patient matching should continue while ensuring that solutions meet the needs of vulnerable populations.</li> </ul>	Hold a listening session to learn more about: <ol style="list-style-type: none"> <li>How to improve the standardization of data linking to support interoperability that increases the quality of the data content and the ability for recipients to request needed data.</li> <li>The TEFCA QHINs' experiences with exchanging data with each other, including how they are implementing cross-QHIN patient matching and supporting vulnerable and diverse populations.</li> <li>Government agencies' experiences with linking clinical and claims data, e.g., the Centers for Disease Control and Prevention (CDC), the FDA, and the National Cancer Institute, and other industries' experience with person matching.</li> <li>Lessons learned that could support the data linking initiatives, e.g., the Privacy Protecting Record Linkage (PPRL) strategy.</li> </ol>
<b>Longer-Term Opportunities</b>			
Supporting Interoperability Standards — Long-Term and Post-Acute Care (LTPAC) Providers	Interoperability needs to be increased across the broader care continuum to include LTPAC providers.	Explore incentives or requirements for LTPAC providers to meet the standards for the Medicare Promoting Interoperability Programs standards.	<ol style="list-style-type: none"> <li>Explore what actions HHS can take to advance LTPAC interoperability including reviewing steps CMS may be taking to incentivize sharing of LTPAC data.</li> <li>Explore certification needs for LTPAC providers' health IT systems to support bi-directional exchange with acute and ambulatory providers that have already adopted certified Health IT Modules.</li> </ol>
Streamlining of Health Information Exchange*	Gaps in interoperability remain when health organizations rely on multiple methods of electronic data exchange and must coordinate across multiple health systems, health IT systems, and health information networks to enable exchange.	Explore the development of implementation guidance that enables increased consistency of the data exchanged.	Identify priority use cases and develop recommendations on implementation guidance that can be used in the field to increase the consistency of the data being shared including via the TEFCA.
<b>Target Area: Privacy and Security</b>			
<b>Immediate Opportunities</b>			
Privacy of Sensitive Health Data — Gender and Reproductive Health	The inconsistent legal landscape governing gender and reproductive health data combined with the difficulty in segmenting this data regularly creates barriers to its exchange.	Identify opportunities to improve technical and operational approaches to protecting sensitive health data regarding gender and reproductive health.	<ol style="list-style-type: none"> <li>Hold a listening session with the HHS Office for Civil Rights (OCR) and others to explore the health IT industry's opportunities to improve the protection of sensitive health data regarding gender and reproductive health.</li> <li>Recommend that ONC consider publishing a Special Emphasis Notice under the LEAP in Health IT funding opportunity to support further work around the privacy of sensitive health data.</li> </ol>



Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Privacy of Sensitive Health Data — Consent	There is a lack of consensus on the key use cases, the definition of sensitive health data, and the path forward to support improved electronic patient consent.	Implement enabling infrastructure to support the interoperable exchange of consent directives.	<ol style="list-style-type: none"> <li>Evaluate the current models and suggest steps toward a terminology value set for sensitive health data elements that could be widely adopted and enable the exchange of computable consent decisions.</li> <li>Explore what additional foundational infrastructure needs to be in place to support the interoperable exchange of consent information.</li> </ol>
Lack of Accounting of Disclosures	Today patients have limited transparency into how their identified and de-identified health data are shared.	<ul style="list-style-type: none"> <li>Define the metadata that needs to be collected to support the implementation of accounting of disclosures.</li> <li>Identify lessons learned from programs in other industries that successfully provide data use transparency.</li> <li>Learn more about patient preferences for disclosures about the sharing of their health data.</li> </ul>	<ol style="list-style-type: none"> <li>Explore the metadata needed to implement prioritized use cases that allow patients and healthcare organizations to understand who is accessing patient data and for what purpose.</li> <li>Explore supporting a pilot of the prioritized use cases to ensure the data shared with patients is meaningful and balances information value with information overload.</li> <li>Explore opportunities to encourage healthcare organizations to regularly provide increased transparency into how they use de-identified data.</li> <li>Explore patient preferences for disclosures about the sharing of their health data.</li> </ol>
Cybersecurity Events Across the Healthcare Infrastructure*	Cybersecurity events continue to block access to health records which can impede patient care.	Mitigate the patient safety risks and financial costs of cybersecurity events.	In collaboration with relevant HHS agencies, hold a listening session to explore best practices across healthcare (with a focus on organizations that have experienced a cybersecurity event) and other industries and amplify existing federal and industry initiatives to improve cybersecurity.

**Target Area: Patient Access to Information**

**Immediate Opportunities**

Limited Guidance for Safety and Security of Mobile Health Apps*	The lack of a uniform public or private approach to oversee the mobile health app field results in inconsistent quality of apps and widely varying privacy and security protections.	For clinically valid apps vetted by third parties (e.g., specialty societies), highlight available guidance and develop certification criteria to support interoperability with other certified Health IT Modules.	Explore the guidance available and certification criteria needed for apps that have been vetted as clinically valid to support interoperability with other certified Health IT Modules.
Patient-Generated Health Data (PGHD) — Lacking Interoperability Standards and Data Access among Devices and Platforms*	<ul style="list-style-type: none"> <li>Accessing PGHD requires special effort for providers and patients to access, including challenges in uploading to EHRs and controlling and directing one's personal data.</li> <li>PGHD device (consumer and medical) and software developers are not subject to health IT certification but play a critical role in the ecosystem.</li> </ul>	Improve standards and metadata to support the incorporation and personal access and control of clinically relevant PGHD collected from health apps, wearable devices (both consumer and medical), and other sources.	<ol style="list-style-type: none"> <li>In collaboration with other relevant federal agencies, review policy considerations and define clinically relevant PGHD that should be available to providers and patients without special effort and for personal and direct control.</li> <li>Explore best practices review policy considerations for improving the usability of PGHD in clinical workflows, including data visualization and other authentication and data access workflows.</li> </ol>



Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
<b>Longer-Term Opportunities</b>			
Patient-Reported Electronic Health Record Update Processes*	Transparency about the accuracy of patient data and an easy electronic mechanism to update incorrect data are still lacking.	Identify best practices to improve existing processes to review and respond to patient-requested changes, considering exchange and privacy concerns.	Hold a listening session to identify current processes healthcare providers are using to receive and process patient-requested changes and explore best practices to improve the current state.
User-Friendly Price/Cost Data Transparency*	Price and coverage data provided for transparency can be difficult to understand.	Expand price transparency efforts and further understand patients' experiences of accessing and using price/cost transparency data.	Invite CMS to provide an update to the HITAC on its healthcare provider and health plan price transparency initiatives.

\*Topics that tend to recur across HITAC annual reports



## HITAC PROGRESS IN FY23

### Summary of HITAC Subcommittee Meetings and Recommendations

The Cures Act directs the HITAC to make recommendations to the National Coordinator regarding policies, standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally, and locally, that advances the electronic access, exchange, and use of health information.

#### Overall Accomplishments in FY23

The HITAC's focus in FY23 was on reviewing and making recommendations on the HTI-1 proposed rule, reviewing the draft USCDI v4, continuing to evaluate the needs of public health data systems, and exploring ways to improve pharmacy interoperability. The HITAC held nine public meetings of the full committee and 61 public meetings of the subcommittees. The HITAC delivered 155 recommendations and its annual report to the National Coordinator.

The full committee, through the work of several subcommittees, developed recommendations to support ONC's work. In FY23, the subcommittees included the:

- Annual Report Workgroup
- HTI-1 Proposed Rule Task Force 2023
- Interoperability Standards Workgroup
- Pharmacy Interoperability and Emerging Therapeutics Task Force 2023
- Public Health Data Systems Task Force 2022

The charges and accomplishments of the subcommittees are as follows:

#### Annual Report Workgroup

The Cures Act requires the HITAC to develop an annual report to be submitted to the Secretary of HHS and Congress each fiscal year. At the HITAC meeting on June 20, 2018, the HITAC formed the [Annual Report Workgroup](#) to address the following charge from ONC:

- *Overarching Charge:* The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the Secretary of Health and Human Services and to Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.
- *Specific Charge:* Provide specific feedback on the content of the report as required by the 21st Century Cures Act including:
  - 1) Analysis of HITAC progress related to the target areas
  - 2) Assessment of health IT infrastructure and advancements in the target areas
  - 3) Analysis of existing gaps in policies and resources for the target areas
  - 4) Ideas for potential HITAC activities to address the identified gaps



## Accomplishments in FY23

The Annual Report Workgroup held nine public meetings in FY23 to develop its recommendations. The HITAC approved the HITAC Annual Report for FY22 for submission to the National Coordinator in February 2023 and subsequent transmittal to the Secretary of HHS and to Congress. The HITAC Annual Report for FY22 reviewed HITAC activities in FY22, described the landscape of health IT infrastructure, identified gaps and opportunities, and offered 46 recommendations for future HITAC activities.

### HTI-1 Proposed Rule Task Force 2023

On April 18, 2023, ONC published the HTI-1 proposed rule. At the HITAC meeting on April 12, 2023, ONC charged the HITAC with providing recommendations on the HTI-1 proposed rule. The HITAC then formed the [HTI-1 Proposed Rule Task Force 2023](#) to address the following charge from ONC:

- **Overarching Charge:** The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule.
- **Specific Charge:** Provide recommendations on ONC's proposals that would:
  - 1) Rename all certification criteria within the ONC Health IT Certification Program (Program) as "ONC Certification Criteria for Health IT" and discontinue year themed "Editions"
  - 2) Establish a new baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3
  - 3) Implement the Electronic Health Record (EHR) Reporting Program as a new Insights Condition and Maintenance of Certification for health IT developers under the Program
  - 4) Enhance information sharing under the information blocking regulations
  - 5) Adopt new and revised standards and certification criteria, including:
    - (a) Electronic case reporting certification criterion
    - (b) Clinical decision support (CDS) and decision support interventions (DSI) certification criteria
    - (c) Application programming interfaces (APIs) for patient and population services
    - (d) FHIR® US Core (IG) STU version 5.0
    - (e) HL7® Clinical Document Architecture (HL7® CDA®) R2 IG: C–CDA Templates for Clinical Notes STUR2.1 Companion Guide, Release 3 US Realm
    - (f) A new patient requested restrictions certification criterion
    - (g) Requirements for health IT developers to update previously certified health IT
  - 6) Establish additional Assurances Condition and Maintenance of Certification requirements
  - 7) Solicit requests for information (RFIs) on Program standards, certification criteria, and information blocking to inform potential future rulemaking

## Accomplishments in FY23

The HTI-1 Proposed Rule Task Force 2023 held 22 public meetings in FY23. The HITAC approved and transmitted 68 recommendations to the National Coordinator in June 2023. The recommendations supported the adoption of USCDI v3 and other proposed standard changes, provided implementation suggestions if ONC discontinues year themed editions, suggested that ONC collaborate with the Food and Drug Administration (FDA) on several items related to DSI, and supported the implementation of the Insights Condition and Maintenance of Certification. The Task Force also provided feedback on RFIs concerned with laboratory data interoperability, clinical decision support hooks, FHIR® subscriptions, information blocking clarifications, and health IT capabilities for data segmentation and patient access.



## Interoperability Standards Workgroup

The Cures Act requires the HITAC to set priorities for standards adoption. On January 17, 2023, ONC published its Draft USCDI v4 and sought public feedback on the data classes and elements included in this version. On January 19, 2023, as part of this public feedback process, ONC charged the HITAC with making specific recommendations on the draft content in USCDI v4. The HITAC then asked the [Interoperability Standards Workgroup](#) to address the following charge from ONC:

- **Overarching Charge:** Review and provide recommendations on the Draft USCDI Version 4
- **Specific Charge:** Evaluate Draft USCDI v4 and provide HITAC with recommendations for:
  - a. New data classes and elements from Draft USCDI v4
  - b. Level 2 data classes and elements not included in Draft USCDI v4

### Accomplishments in FY23

The Interoperability Standards Workgroup held 12 public meetings in FY23. The HITAC approved and transmitted 34 recommendations to the National Coordinator in April 2023. The recommendations supported the addition of the new proposed data elements and data classes in USCDI v4, suggested clarifications to data elements and data classes, and suggested level 2 data classes and elements not included in USCDI v4.

## Pharmacy Interoperability and Emerging Therapeutics Task Force 2023

At the HITAC meeting on June 15, 2023, ONC charged the HITAC with providing recommendations on improving pharmacy interoperability. The HITAC then formed the [Pharmacy Interoperability and Emerging Therapeutics Task Force 2023](#) to address the following charge from ONC:

- **Overarching Charge:** Identify recommendations to support interoperability between pharmacy constituents, and the exchange of information necessary for medication management, patient safety, and consumer engagement.
- **Specific Charge:**
  - 1) Public Health, Emergency Use Authorizations, and Prescribing Authorities
    - a. Short-term
      - i. Identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions.
      - ii. Are there actions ONC can take to enable data exchange in support of public health emergency use cases? For example, Test to Treat and COVID-19 treatment prescribing?
    - b. Long-term
      - i. Recommendations to better integrate pharmacy systems and data for public health surveillance, reporting, and public health interventions.
  - 2) Identify opportunities and recommendations to improve interoperability between pharmacy constituents (prescribers, pharmacists, pharmacy benefit managers, dispensers, payers, intermediaries, PDMPs, public health agencies, HIEs, third party service providers, consumers, etc.) for pharmacy-based clinical services and care coordination.
    - a. How can ONC help facilitate adoption and use of standards to support data exchange for pharmacy-based clinical services?
    - b. Which priority pharmacy-based clinical use cases should ONC focus on in the short-term and long-term?





- c. What technology gaps exist for pharmacists to participate in value-based care?
- d. What can ONC do to address drug inventory transparency for prescribers and consumers?
- 3) Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.
  - a. What standards gaps exist for the prescribing and management of:
    - i. specialty medications
    - ii. digital therapeutics
    - iii. gene therapies
- 4) Identify policy and technological needs and considerations for direct-to-consumer medication services.

### Accomplishments in FY23

The Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 held 12 public meetings in FY23. The HITAC approved and transmitted 34 recommendations to the National Coordinator in November 2023. The recommendations suggested ways to advance the ability of pharmacists to capture data for their own benefit and for other care team members, providers, and public health agencies. They also identified interoperability capabilities of particular interest (e.g., pre-authorization, two-way communication between a pharmacy and a patient or caregiver) and suggested that pharmacy services-focused quality measures should be developed.

### Public Health Data Systems Task Force 2022

At the HITAC meeting on August 19, 2022, ONC charged the HITAC with providing recommendations on improving public health data systems. The HITAC then formed the [Public Health Data Systems Task Force 2022](#) to address the following charge from ONC:

- **Overarching Charge:** The Public Health Data Systems Task Force 2022 will build upon recommendations from previous HITAC public health-focused task forces to inform ONC's continued collaborative work with CDC on improving public health data systems, and in support of CDC's greater Data Modernization Initiative (DMI) efforts.
- **Specific Charge:**
  - 1) The Public Health Data Systems Task Force 2022 shall examine existing public health certification criterion, known as the "(f) criteria" in the ONC Health IT Certification Program, certifying the transmission of data to public health agencies to:
    - a. Identify gaps in the functionalities and standards included in existing (f) criteria, including gaps in 1) functionality, and 2) implementation by developers. Provide recommendations advancing criteria, testing guidance, and/or standards to address gaps.
    - b. Assess the specific functions (e.g., receipt of data, ingestion of data, analysis of data) supported by public health data systems that would benefit from further standardization and potential certification.
    - c. Recommend which data flows, aligned with existing (f) criteria, should be prioritized for standardized receipt of data.



### Accomplishments in FY23

The Public Health Data Systems Task Force 2022 held six public meetings in FY22 and another six public meetings in FY23. The HITAC approved and transmitted 53 recommendations to the National Coordinator in November 2022. The recommendations focused on establishing certification criteria for technologies used for public health for interoperability functions such as the exchange, access, and use of messages that are efficient and effective, whether or not correctly formatted, and complete. The recommendations also focused on changes and additions to the existing public health certification criteria.

## CONCLUSION

Significant progress was made in advancing the use of technologies that support health equity, public health, interoperability, privacy and security, and patient access to information in FY23. However, work remains in these target areas to achieve the full potential of using health IT tools to help transform the healthcare sector. In FY24, ONC and the HITAC will continue to focus on advancing the implementation of the health IT provisions of the Cures Act including the TEFCA, as well as address evolving issues including health equity and public health-related technology concerns, contributions to the USCDI, and priority uses of health IT and related standards and specifications.



## APPENDIX

### ONC Objectives and Benchmarks

As required by the Cures Act, ONC established a set of objectives and benchmarks against which to measure the advancement of the target areas during FY23-24, outlined below. ONC has defined the benchmarks as progress toward measures of achieving milestones in activities related to Standards, Certification, Exchange, and Coordination.

#### ONC Objectives in FY23-24

1. Advance the development and use of health IT capabilities.
2. Establish expectations for data sharing.

#### ONC Benchmarks in FY23-24

ONC Activity	FY23 Progress	FY24 Benchmarks
Coordination	<p><i>Health Equity by Design</i></p> <ul style="list-style-type: none"> <li>• Continued to prioritize the addition of USCDI data elements that advance health equity including:                             <ul style="list-style-type: none"> <li>○ Treatment intervention preference</li> <li>○ Care experience preference</li> <li>○ Alcohol use</li> <li>○ Substance use</li> <li>○ Physical activity</li> </ul> </li> <li>• Published HL7 Cross Paradigm IG: Gender Harmony - Sex and Gender Representation.</li> <li>• Trained over 1300 students in public health informatics and technology through the PHIT Program as of October 31, 2023.</li> </ul>	<p><i>Health Equity by Design</i></p> <ul style="list-style-type: none"> <li>• Advance adoption and use of USCDI data classes and elements that support health equity, including:                             <ul style="list-style-type: none"> <li>○ Sexual orientation and gender identity</li> <li>○ Functional, disability, and mental/cognitive status</li> <li>○ Social determinants of health such as food, housing, and transportation insecurity</li> </ul> </li> <li>• Continue to train students through the PHIT Workforce Development Program in public health informatics and data science at minority serving institutions and other colleges and universities.</li> </ul> <p><i>ONC Rulemaking</i></p> <ul style="list-style-type: none"> <li>• Publish HTI-1 final rule.</li> <li>• Publish Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule.</li> </ul>
Standards	<p><i>USCDI</i></p> <ul style="list-style-type: none"> <li>• Published USCDI Version 4, which includes one new data class and 20 new data elements.</li> <li>• Some of the new data elements address health equity and public health concerns.</li> </ul>	<p><i>USCDI</i></p> <ul style="list-style-type: none"> <li>• Release USCDI Version 5 with additional data classes and data elements.</li> </ul>
	<p><i>USCDI+</i></p> <p>USCDI+ collaborations underway:</p> <ul style="list-style-type: none"> <li>• Public Health (with CDC)</li> <li>• Quality (with CMS)</li> <li>• Uniform Data System Reporting (with HRSA)</li> </ul>	<p><i>USCDI+</i></p> <ul style="list-style-type: none"> <li>• Expand use cases and projects under the current domains (Quality, Public Health, Cancer, Behavioral Health, and Maternal Health).</li> <li>• Finalize datasets under Public Health Domain, including Case Reporting, Laboratory Exchange, and Situational Awareness and Emergency Response use cases.</li> </ul>



ONC Activity	FY23 Progress	FY24 Benchmarks
	<p><b>Standards Version Advancement Process (SVAP)</b></p> <ul style="list-style-type: none"> <li>• Approved 6 standards.</li> <li>• Advanced health equity work through key patient demographic data.</li> <li>• Supports industry on consistent implementation of:                             <ul style="list-style-type: none"> <li>○ USCDI Version 3</li> <li>○ US Core FHIR® IG v6.1.0</li> <li>○ CMS IG for Quality Reporting Document Architecture</li> </ul> </li> </ul>	<p><b>SVAP</b></p> <ul style="list-style-type: none"> <li>• Publish National Coordinator-approved updated versions of health IT standards and implementation specifications.</li> </ul>
	<p><b>HL7® FHIR®</b></p> <ul style="list-style-type: none"> <li>• Published U.S. Core FHIR® IG v6.1.0 including updates to support USCDI Version 3.</li> <li>• Published HL7® Cross Paradigm IG: Gender Harmony - Sex and Gender Representation.</li> <li>• Provided ongoing development and support for International Patient Summary (IPS) FHIR® IG.</li> </ul>	<p><b>HL7® FHIR®</b></p> <ul style="list-style-type: none"> <li>• Develop and publish updates to FHIR® Bulk Data IG.</li> <li>• Develop and publish U.S. Core FHIR® IG v7.0.0 including updates to support USCDI v4.</li> <li>• Support standards development related to emerging FHIR® capabilities such as FHIR® write, SMART Health Links, SMART App Launch IG granular scopes, and consent.</li> <li>• Offer ongoing development and support for FHIR® infrastructure including the FHIR® IG publisher and FHIR® validator.</li> </ul>
	<p><b>Public Health</b> Supported the Helios Public Health FHIR® Accelerator initiative:</p> <ul style="list-style-type: none"> <li>• Successfully tested use of Bulk FHIR® IG to support the Bulk Query of Immunization Information Systems (IIS) through two Connectathon events.</li> <li>• Successfully tested components of Situation Awareness for Novel Epidemic Response (SANER) and Data Exchange for Quality Measures (DEQM) IG to support the “Aggregate Data” project within Helios.</li> <li>• Established project to test public health query of FHIR® APIs for case follow-up information, with successful testing at Connectathon.</li> </ul>	<p><b>Public Health</b></p> <ul style="list-style-type: none"> <li>• Incorporate USCDI+ into Standard Development Organization activities and FHIR® profile development.</li> <li>• Initiate production pilots for Query and Response, Bulk Query, and Aggregate Data projects.</li> <li>• Establish new project area for “Public Health Reporting”, test new Vital Records use case for “Bulk Query.”</li> </ul>
	<p><b>HHS-Wide Approach on Health IT Standards Investments</b></p> <ul style="list-style-type: none"> <li>• ONC and the HHS Assistant Secretary for Financial Resources (ASFR) began operationalizing the HHS Health IT Alignment policy.</li> <li>• ONC and HHS divisions identified a broad range of applicable grants, cooperative agreements, contracts,</li> </ul>	<p><b>HHS-Wide Approach on Health IT Standards Investments</b></p> <ul style="list-style-type: none"> <li>• Spring 2023 Unified Agenda includes HHS Acquisition Regulation: Standards for Health Information Technology proposed rule.</li> <li>• Maximize opportunities to align standard health IT language in applicable grants, cooperative agreements, contracts, and rulemaking/guidance</li> </ul>



ONC Activity	FY23 Progress	FY24 Benchmarks
	and rulemaking/guidance – covering public health, emergency preparedness, research, and other areas – for incorporating standard health IT language.	to ensure alignment of HHS health IT investments. <ul style="list-style-type: none"> <li>Engage with HHS agencies on health IT-related activities.</li> </ul>
Certification	<i>Certification Program and Testing Requirements</i> <ul style="list-style-type: none"> <li>Successfully managed implementation of Cures Update criteria, including the update of 98% of all eligible Health IT Modules to the standardized API criterion, with minimal conformance disruption.</li> <li>Continued program support of SVAP with 45 developers taking advantage of the policy.</li> <li>Completed first cycle of Real-World Testing with results reporting in March 2023, maintaining 100% compliance rate.</li> </ul>	<i>Certification Program and Testing Requirements</i> <ul style="list-style-type: none"> <li>All certified Health IT Modules that are part of a health IT product that stores electronic health information are required to certify to the Electronic Health Information export criterion (45 CFR 170.315 (b)(10)) and make the functionality available to end users by December 31, 2023.</li> <li>Expand Test Tool Suite to include electronic prescriptions and additional Inferno test kits including CARIN Blue Button specification to support adoption.</li> </ul>
Exchange	<i>TEFCA</i> <ul style="list-style-type: none"> <li>New 5-year TEFCA RCE contract in place with The Sequoia Project</li> <li>Application portal now open to potential QHINs</li> <li>Candidate QHINs progressing through application and onboarding</li> <li>Payment and Health Care Operations Standard Operating Procedures (SOPs) in development</li> <li>Public Health SOP and associated implementation guides in development</li> </ul> <i>Information Blocking</i> <ul style="list-style-type: none"> <li>HHS Office of the Inspector General (OIG) Final Rule published, and enforcement of the information blocking penalties began on September 1, 2023.</li> <li>ONC received 365 submissions through the ONC Report Information Blocking Portal.</li> </ul>	<i>TEFCA</i> <ul style="list-style-type: none"> <li>Publish Final Common Agreement (CA) v2 and the Qualified Health Information Network (QHIN) Technical Framework (QTF) v2 to include a TEFCA Facilitated FHIR® IG.</li> <li>Continue to support QHIN applications, onboarding process, and transition to become fully operational/go-live</li> <li>Continue to support the expansion of exchange mechanisms to include FHIR® within TEFCA.</li> <li>Continue TEFCA education activities, including through SOPs, public webinars, and frequently asked questions (FAQs).</li> </ul> <i>Information Blocking</i> <ul style="list-style-type: none"> <li>HHS "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" proposed rule is published.</li> <li>Coordinate with OIG on Information Blocking claims.</li> <li>Offer continued support for the Information Blocking Portal to receive information blocking claims.</li> </ul>



## FY23 HITAC Member list

- Medell Briggs-Malonson, Co-Chair, UCLA Health\*
- Aaron Miri, Co-Chair, Baptist Health\*
- Shila Blend, Member, North Dakota Health Information Network
- Hans Buitendijk, Member, Oracle Health\*
- Sarah DeSilvey, Member, Gravity Project
- Steven (Ike) Eichner, Member, Texas Department of State Health Services
- Cynthia A. Fisher, Member, Patient Rights Advocate
- Lisa Frey, Member, St. Elizabeth Healthcare
- Hannah Galvin, Member, Cambridge Health Alliance\*
- Rajesh Godavarthi, Member, MCG Health, part of the Hearst Health network
- Valerie Grey, Member, State University of New York
- Steven Hester, Member, Norton Healthcare
- Bryant Thomas Karras, Member, Washington State Department of Health
- Kensaku Kawamoto, Member, University of Utah Health
- Steven Lane, Member, Health Gorilla
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- Deven McGraw, Member, Invitae Corporation
- Aaron Neinstein, Member, Notable
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- Kikelomo Oshunkentan, Member, Pegasystems
- Naresh Sundar Rajan, Member, CyncHealth
- Alexis Snyder, Member, Individual
- Fillipe Southerland, Member, Yardi Systems, Inc.
- Sheryl Turney, Member, Elevance Health
- Jim Jirjis, Federal Representative, Centers for Disease Control and Prevention\*
- Meg Marshall, Federal Representative, Department of Veterans Health Affairs
- Michelle Schreiber, Federal Representative, Centers for Medicare & Medicaid Services
- Ram Sriram, Federal Representative, National Institute of Standards and Technology

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## Acknowledgements

### ONC

- Michael Berry, retired
- Michelle Murray
- Seth Pazinski

### Audacious Inquiry

- Michelle Consolazio
- Eliana Donner-Klein
- Marla Durben Hirsch
- Kory Mertz
- Kim Poletti