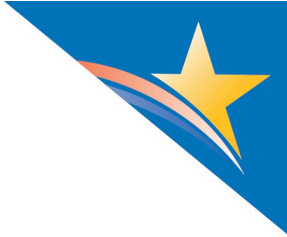


Health Information Technology Advisory  
Committee (HITAC)  
Annual Report for Fiscal Year 2022

**FEBRUARY 8, 2023**

**REVISED PREDECISIONAL DRAFT**



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## FOREWORD

We are pleased to present the annual report of the HITAC for FY22.

This report describes the work undertaken by the HITAC during its fifth 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 within 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 FY22, the HITAC made recommendations on the existing set of ONC-adopted standards and implementation specifications, priority uses of health IT, the United States Core Data for Interoperability (USCDI), and public health data systems. Several areas for potential future HITAC work surfaced during the HITAC meetings in FY22, and a robust discussion among the members yielded several areas for potential activity in fiscal year 2023 (FY23) 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. We wish to also express our sincere thanks to the previous HITAC co-chair during 2021 and 2022, Denise Webb. 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. We look forward to another busy year as we continue 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.

Aaron Miri and Medell Briggs-Malonson  
Co-Chairs, Health Information Technology Advisory Committee



## INTRODUCTION

The 21st Century Cures Act (Cures Act) requires the Health Information Technology Advisory Committee (HITAC) to develop an annual report to be submitted to the Secretary of the United States (U.S.) Department of Health and Human Services (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 fiscal year 2022 (FY22) 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

A patient goes to a community hospital to see a new primary care physician (PCP). During the intake session, the hospital uses a CDS tool to conduct the interview and screening of the patient, who notes that their gender identity is non-binary. Historically, the electronic health record (EHR) only allowed providers to indicate a gender of male or female. Through the Health Equity by Design initiative, certified health IT now includes improved options to capture patient demographics that are then used to inform CDS and other tools. The PCP implements best-practice CDS recommendations that reduce the likelihood of unintentional bias to ensure that the patient receives gender-affirming care at the community hospital.

Health equity is achieved when everyone has a fair and just opportunity to attain their highest level of health. The intentional design and implementation of health information technology infrastructures, policies, and practices are needed to identify and mitigate clinical and social inequities that contribute to unjust variations in health between populations. Efforts are underway to promote health equity by design to ensure that equity considerations are included when building health IT tools and creating health programs, including by ONC. Data collection and analysis are important tools in identifying and addressing health equity gaps. Versions 2 and 3 of the USCDI added health equity-related data elements to improve the collection of this data. Standards efforts are underway to improve the interoperability of social determinants of health (SDOH) data, including assessments. Artificial intelligence (AI), machine learning, and clinical decision support (CDS) tools have the potential to improve health care for patients but also to exacerbate existing care inequities if they contain biases or use biased data. The Biden Administration has published a [set of principles and associated practices](#) for building and deploying automated systems and AI that includes algorithmic discrimination protections.



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



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

A patient presents at an urgent care center with symptoms of monkeypox, now called mpox. The urgent care center collects an appropriate sample and has it transported safely to a laboratory. The urgent care center electronically notifies the local and public health authorities using electronic case reporting (eCR) to share important clinical and demographic information (e.g., date of onset of symptoms, address, and phone number) and close contacts for contact tracing. Within 48 hours from when the patient presented to the urgent care center, the laboratory confirms that the patient has tested positive for mpox. Due to improvements in the healthcare and public health infrastructure, electronic notifications are sent to the urgent care center, the public health authorities, and the patient's PCP that the patient has tested positive for mpox. This electronic notification enables a quick response by public health and providers to help contain the spread of the virus.

The COVID-19 pandemic demonstrated a need to significantly improve the collection and use of critical health data at all levels of public health while reducing the burden placed on those who provide and collect the data. The Centers for Disease Control and Prevention's (CDC) [Data Modernization Initiative](#) (DMI) is working to transform siloed and brittle public health data systems into connected, resilient, adaptable, and sustainable "response-ready" systems that can help solve problems before they occur. ONC and the CDC are collaborating on initiatives to improve existing standards and support the use of the Health Level 7 International (HL7<sup>®</sup>) Fast Healthcare Interoperability Resources (FHIR<sup>®</sup>) standard in public health. New steps have been taken to improve public health reporting and address workforce gaps.

## Target Area: Interoperability



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

An academic medical center is conducting a pilot to evaluate how improving referrals and addressing social needs like food insecurity and transportation impact diabetes outcomes. Once a patient with diabetes is seen at the emergency department (ED) and meets the criteria for the pilot's determined social needs, the ED clinician uses a standardized provider directory to refer the patient to an endocrinologist in the patient's health insurance network. As a result of streamlining electronic prior authorization processes, the academic medical center can reduce unnecessary administrative burden to facilitate the referral. To address the patient's social needs, the patient is referred to a community-based organization for transportation and food insecurity support. Using a recently adopted closed-loop referral system, the academic medical center is updated that the referrals have been received and acted upon. The patient is now seeing an endocrinologist with the aid of transportation support and receiving daily healthy meals from the community-based organization.

The health information ecosystem continues to strive for improved interoperability. Health information networks continue to consolidate and partner to share services across states to better support the evolving needs of patients, providers, and others, and national networks are growing and expanding their supported use cases. Interoperability remains fragmented, pointing to needs for better patient matching, improved provider directories, closed-loop referrals to coordinate care, and prior authorization to reduce provider burden. The usage of telehealth services increased significantly during the COVID-19 pandemic but continues to present unique interoperability and health equity considerations.



## Target Area: Privacy and Security



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

A behavioral health clinic covered by 42 CFR Part 2 participates in the Trusted Exchange Framework and Common Agreement (TEFCA) and has a clear understanding of when it can and cannot respond to information requests based on the information-blocking guidelines ONC issued. Leveraging TEFCA implementation guides, the clinic has a standardized mechanism to comply with the HIPAA minimum necessary requirements when sharing data for healthcare operations and payment purposes. In addition, based on lessons learned from other providers who participate in TEFCA, the clinic has developed an effective methodology for sending and receiving required consents using TEFCA. These clarifications lessen confusion around privacy and consent for this clinic and others like it.

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 and covered entities are still confused about the privacy and security of data not subject to the Health Insurance Portability and Accountability Act (HIPAA) and how this data can be used. A gap has developed between the boundaries of regulation and the capabilities of technology, creating challenges for both developers and regulators. Today, health IT systems cannot reliably segment and produce discrete pieces of data, which hinders their ability to comply with HIPAA's minimum necessary requirements and exchange sensitive health data.

## Target Area: Patient Access to Information



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

A voluntary program has been established by health IT industry partners that verifies that consumer-oriented health apps produce clinically validated recommendations, protect the privacy of patients' data, and demonstrate cultural and linguistic sensitivity. A patient with cardiovascular conditions from a community with a large immigrant population is looking for a Spanish-language health app to assist her in monitoring her high blood pressure and integrating her related health data from several provider organizations and her preferred laboratory and pharmacy. While searching the app store on her phone, she finds apps that display the program's seal of approval. She chooses a verified Spanish-language app knowing it will protect her data and provide accurate care recommendations.

Sharing health information with patients in a timely manner supports patients' autonomy in their health care while improving patient-provider communication. As more patients use mobile health applications, concerns have arisen regarding whether they are reliable, effective, and designed to support all patient populations and underserved populations in particular. The federal government has taken several steps to improve cost and coverage transparency; however, challenges remain. Patients often still face barriers to accessing, using, and consolidating their health information from multiple providers.



## Federal Activities across the Target Areas

In FY22, the federal government advanced several initiatives to improve health IT. ONC continued its implementation of the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). The covered dataset for information blocking was no longer limited to the USCDI Version 1 and instead to the definition of [electronic health information](#) (EHI). New ONC Health IT Certification Program requirements went into effect, including the application programming interface (API) provisions, real-world testing, and attestation for compliance with the Conditions and Maintenance of Certification requirements. ONC and its Recognized Coordinating Entity (RCE), The Sequoia Project, announced the implementation of the Trusted Exchange Framework and Common Agreement (TEFCA), and the RCE has taken steps to operationalize it. The application process for Qualified Health Information Networks (QHINs) opened in October 2022. ONC continued working with federal partners to support their data needs through the USCDI+ initiative and the final Project US@ standards were published.

## 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 2023-24, while longer-term opportunities are anticipated to begin in three or more years, i.e., calendar year 2025 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>			
Health Equity by Design	Ongoing efforts promote equity as a core design feature of health IT initiatives. However, many health IT systems and initiatives were not designed with health equity in mind.	<ul style="list-style-type: none"> <li>Promote “health equity by design” in health IT initiatives.</li> <li>Define health equity, healthcare equity, and health data equity/data justice.</li> </ul>	<ol style="list-style-type: none"> <li>Explore ways the ONC Health IT Certification Program can support health equity by design to advance health equity and data justice.</li> <li>Explore the development of metrics to track progress on the inclusion of health equity by design in the ONC Health IT Certification Program.</li> <li>Consider the creation of an Equity Officer at ONC or the recruitment of equity leaders in the HITAC to guide these efforts.</li> </ol>
Inequities in Data Collection	Inequities in data availability and use often stem from inequities in data collection. When it is collected, health equity-related data is often collected inconsistently among and within sources.	<ul style="list-style-type: none"> <li>More industry standards supporting the collection and integration of health equity data elements could be established and agreed upon.</li> <li>The exchange of supplemental data could be increased to provide missing race, ethnicity, language, and SDOH data.</li> </ul>	<ol style="list-style-type: none"> <li>Explore the adoption of improved standards for capturing patient demographics, including race, ethnicity, language, sexual orientation, gender identity, and faith, in a manner that does not over-generalize patients.</li> <li>Hold a listening session to:</li> </ol>



Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
		<ul style="list-style-type: none"> <li>Collection directly from patients could enhance the precise capture of these elements.</li> </ul>	<ol style="list-style-type: none"> <li>identify best practices at registration and other relevant collection points, including through patient portals and apps, to improve the collection and validation of health equity data; and</li> <li>explore opportunities to increase the use of data enrichment strategies to bring together multiple data sources to add missing health equity data elements.</li> </ol>
Electronic Exchange of Health Equity and Social Determinants of Health Data	The electronic exchange of health equity and SDOH data, even when it is available electronically, remains uneven.	<ul style="list-style-type: none"> <li>Promote best practices for the electronic exchange of health equity and SDOH data.</li> <li>Move toward unified and consistent race, ethnicity, and language standards.</li> </ul>	<ol style="list-style-type: none"> <li>Explore opportunities within HHS to incentivize the standardized exchange of health equity and SDOH data.</li> <li>Explore the opportunity to incentivize the use of vulnerability indices through the ONC Health IT Certification Program.</li> <li>Inventory state reporting requirements for health equity and SDOH data.</li> </ol>
Bias Concerns – Algorithms, Clinical Decision Support Tools, and Patient Interview/ Questionnaire Data	The design of AI algorithms raises concerns about implicit biases in machine learning (e.g., regarding gender, race, and ethnicity). CDS tools may also contain implicit biases that impact care decisions or be applied inappropriately. Biases of standardized survey instruments and individuals conducting patient interviews may impact data entered in patient records.	<ul style="list-style-type: none"> <li>Screen healthcare and public health data systems for bias in surveys, questionnaires, algorithms, and CDS tools to improve data used for decision-making.</li> <li>Encourage the use of digital tools to support clinicians in conducting unbiased patient interviews and screenings.</li> </ul>	<ol style="list-style-type: none"> <li>Hold a listening session, in collaboration with relevant HHS agencies, focused on developing best practices to prevent unintentional bias in machine learning and address existing algorithms, CDS tools, and patient interview techniques that perpetuate health inequities.</li> <li>Explore the impact of the use of sexual orientation and gender identity (SO/GI) data elements in AI and CDS to support appropriate clinical care aligned with patients' identities and preferences.</li> <li>Perform a literature review and produce a summary report on the current state, gaps, and opportunities in these areas.</li> </ol>
<b>Target Area: Use of Technologies that Support Public Health</b>			
<b>Immediate Opportunities</b>			
Public Health Data Systems – Infrastructure	Coordination and standardization are needed to reduce gaps that impede the sharing of data important to public health.	<ul style="list-style-type: none"> <li>Improve the bidirectional exchange of health information between public health and healthcare providers.</li> </ul>	Learn about the status of federal resources and modernization efforts for public health and identify where these resources and efforts need to be coupled with health IT policy and guidelines to accelerate progress.
Public Health Data Reporting – Electronic Case Reporting (eCR)	The rapid expansion and adoption of eCR have enhanced communication between clinicians and public health authorities; however, improvements are still needed.	<ul style="list-style-type: none"> <li>Expand the adoption and support for eCR by public health authorities, healthcare providers, and health IT developers. In particular, more and better standards are needed, and their use encouraged.</li> </ul>	<ol style="list-style-type: none"> <li>Collaborate with convening groups across federal, state, tribal, local, and territorial governments and healthcare provider and laboratory associations to encourage both adoption and advancement of the technology and standards supporting bidirectional data exchange for public health purposes.</li> <li>Explore requiring the use of Interoperability Standards Advisory (ISA)-identified standards for bidirectional eCR in the ONC Health IT Certification program.</li> <li>Explore the development of metrics to track progress on the adoption and use of bidirectional eCR by public health authorities, healthcare providers, and laboratories.</li> </ol>





Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Public Health Data Reporting – Electronic Laboratory Reporting (ELR)	ELR adoption has increased, but standardization is needed to ensure consistency across systems.	<ul style="list-style-type: none"> <li>Improve alignment of standards used by public health authorities, laboratories, healthcare providers, and health IT developers. In particular, the use of terminology standards could be improved.</li> </ul>	Please refer to Recommendations 36-43 in the <a href="#">HITAC's report to the National Coordinator on Public Health Data Systems</a> .
Public Health Data Reporting – Syndromic Surveillance	Syndromic surveillance today is often limited to acute care settings.	Prepare for large-scale data needs outside of outbreaks and pandemics by expanding syndromic surveillance beyond acute care settings.	<ol style="list-style-type: none"> <li>Encourage ONC to work with the CDC and public health organizations to expand participation in syndromic surveillance to include home health care, long-term post-acute care (LTPAC), community-based, and telehealth settings.</li> <li>Hold a listening session from current national data networks that can be leveraged for surveillance.</li> </ol>
Public Health Informatics Workforce	Challenges remain to establishing and maintaining a well-equipped public health workforce.	<ul style="list-style-type: none"> <li>Improve the IT capabilities and capacity of the public health workforce.</li> <li>Define career pathways to attract talent into the public health informatics workforce.</li> </ul>	<ol style="list-style-type: none"> <li>Hold a listening session to learn about progress from existing federal initiatives to increase the capacity of the public health workforce.</li> <li>Identify funding pathways that would support public health organizations to hire and retain public health informatics workforce staff to maintain the public health informatics activities identified by ONC, the CDC, and other federal agencies.</li> </ol>
<b>Target Area: Interoperability</b>			
<b>Immediate Opportunities</b>			
Streamlining of Health Information Exchange	While electronic data exchange adoption continues to grow, interoperability between different health IT systems remains a challenge.	Leverage TEFCA to advance interoperability and reduce the number of methods of electronic exchange health organizations need to use.	Hold a listening session around SDOH data exchange which in some cases are referred to Community Information Exchanges and are intended to support SDOH and health equity efforts.
Interoperability Standards Priority Uses – Closed-Loop Referrals	There is a lack of cross-organization support for closed-loop referrals, including for social services.	<ul style="list-style-type: none"> <li>Explore the opportunities to advance standards that can improve systems for closed-loop referrals.</li> <li>Explore opportunities to increase the adoption of electronic systems by social services organizations, including financial incentives.</li> <li>Explore opportunities to increase patient participation in social referrals.</li> </ul>	<ol style="list-style-type: none"> <li>Hold a listening session to learn about existing progress (e.g., with the 360X Project) and determine additional opportunities to advance closed-loop referrals.</li> <li>Identify priority areas to advance data standards adoption across both health and social support sectors (e.g., education, transportation, food insecurity).</li> </ol>
Equitable Use of Telehealth	<p>Unique interoperability considerations exist for the equitable use of telehealth to help reduce the digital divide.</p> <p>While an increasing number of telehealth providers access patient health data by leveraging the existing interoperability framework, many do not. Few telehealth providers make their documentation readily available for query by other members of patients' care teams.</p>	<ul style="list-style-type: none"> <li>Improve bidirectional exchange between telehealth providers and a patient's care team.</li> <li>Enhance patients' ability to engage social and healthcare providers through telehealth while eliminating inequities and risks for underserved populations.</li> </ul>	Explore the benefits and challenges of encouraging and incentivizing the equitable adoption and use of certified health IT by telehealth providers to support bidirectional exchange.



Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Interoperability Standards Priority Uses – Electronic Prior Authorization*	There is a lack of common standards to support electronic prior (e-prior) authorization across payers.	Explore the opportunities to advance standards that can improve systems for prior authorizations.	Continue to monitor implementation of existing HITAC e-prior authorization recommendations, including updates from industry partners and on related HHS initiatives such as the ONC and CMS rules.
Standards for Patient Matching*	Patient matching when sharing data needs to be improved, especially for vulnerable populations.	<ul style="list-style-type: none"> <li>Address alignment of incentives and certification programs across domains to encourage an ecosystem-based approach to improve patient matching that focuses on setting goals rather than mandating methods.</li> <li>Explore the development of standards that enable the linking of de-identified data.</li> </ul>	<ol style="list-style-type: none"> <li>Hold a listening session with relevant federal agencies (e.g., NIST, DHS, and DoD) to identify best practices to improve patient matching in varying patient populations.</li> <li>Explore other industries' experiences with linking de-identified data as well as healthcare-specific efforts.</li> </ol>
<b>Longer-Term Opportunities</b>			
Provider Directory Standards and Management*	Industry partners struggle to find the digital contact information for healthcare providers for health information exchange.	Improve the availability of electronic endpoints.	Explore opportunities and challenges to supporting the adoption of directory standards and management approaches that support complete, accurate, and usable electronic endpoint directories.
<b>Target Area: Privacy and Security</b>			
<b>Immediate Opportunities</b>			
Appropriate Exchange and Use of Data	Complying with the HIPAA minimum necessary standard is difficult without improved electronic data segmentation capabilities.	<ul style="list-style-type: none"> <li>Promote the development and adoption of implementation guides that support improved data segmentation capabilities.</li> <li>Explore opportunities to reduce the burden on healthcare providers of tracking the evolving privacy landscape across the nation.</li> </ul>	<ol style="list-style-type: none"> <li>Track work underway in TEFCA to adopt use cases that support the exchange of data for treatment, payment, and healthcare operations.</li> <li>Hold a listening session to identify the current state of existing privacy harmonization efforts and best practices to reduce provider burden in tracking the evolving privacy landscape across the nation.</li> </ol>
Privacy of Sensitive Health Data	There is a lack of standards supporting the segmentation of sensitive health data, including for women, pediatric, and gender-diverse populations.	<ul style="list-style-type: none"> <li>Improve industry partners' understanding of existing privacy protections.</li> <li>Identify opportunities to improve technical and operational approaches to protect sensitive health data.</li> </ul>	<ol style="list-style-type: none"> <li>Encourage ONC to provide guidance on the applicability of information-blocking exceptions to the exchange of sensitive data, including reproductive health data.</li> <li>Suggest steps toward a consistent technical and operational approach to protecting sensitive health data while enabling its exchange, including with healthcare apps.</li> </ol>
Cybersecurity Events across the Healthcare Infrastructure*	Cybersecurity events continue to increase.	Offer guidance to the healthcare sector on ways to improve cybersecurity preparedness.	Hold a listening session to explore and amplify existing federal and industry initiatives to improve healthcare cybersecurity, such as cybersecurity insurance. The session should include best practices and how healthcare organizations can partner with both government and industry.
<b>Longer-Term Opportunities</b>			
Alignment of Innovation and Regulation	Clinicians and hospital systems are adopting APIs but are concerned about unauthorized data exposure and added liability.	<ul style="list-style-type: none"> <li>Encourage the health IT industry to accelerate innovation in areas where existing regulations are in place.</li> <li>Understanding of the laws regarding the unauthorized use of APIs as well as of gaps in current legislation could be enhanced.</li> </ul>	<ol style="list-style-type: none"> <li>Learn about federal regulatory activities affecting privacy and security for areas of health IT innovation, especially APIs.</li> <li>Support awareness and education for providers, patients, and other interested parties about relevant federal regulatory activities.</li> <li>Support the development of guidelines that assist provider organizations in more efficiently resolving concerns around data access.</li> </ol>



Topic	Key Gaps	Key Opportunities	Recommended HITAC Activities
Alignment of Innovation and Regulation for Consent Directives	The pace of industry innovation is sometimes faster than that of the regulatory environment for consent directives.	Support the adoption of common standards to capture and exchange electronic consent directives.	<ol style="list-style-type: none"> <li>1. Explore lessons learned from the implementation of consent in the TEFCA program.</li> <li>2. Hold listening sessions to learn about different methodologies and strategies under development and being adopted nationally for distributed and/or centralized consent management.</li> </ol>
<b>Target Area: Patient Access to Information</b>			
<b>Immediate Opportunities</b>			
Patient Consolidation of Health Information from Multiple Sources	Challenges persist in patients' ability to access, consolidate, and share their health information across multiple sources (e.g., portals, labs, payers, and other health IT systems), and consolidate their data into a single system view providing integrated data view and utilization.	<ul style="list-style-type: none"> <li>• Patients need streamlined access, consolidated viewing, and increased visibility and control of sharing of patient data.</li> <li>• Support the development of apps that address the needs of underserved communities.</li> </ul>	<ol style="list-style-type: none"> <li>1. Propose a plan to monitor and assess the successes and challenges with the implementation of the 2015 Edition Cures Update API criteria.</li> <li>2. Explore opportunities (e.g., HHS challenges) to support the development of apps targeted to the unique needs of underserved communities.</li> <li>3. Hold listening sessions on initiatives that have attempted solutions on this front (e.g., Blue Button 2.0, HL7® Carin Accelerator).</li> </ol>
Safety and Impact of Mobile Health Apps*	There is a lack of meaningful analyses of mobile health app efficacy as well as guidance on data security.	Support awareness and education for providers and patients regarding the validity and safety of mobile health applications.	<ol style="list-style-type: none"> <li>1. Explore the ecosystem of vetting the efficacy and security of mobile health apps, including recent industry research and federal regulatory efforts.</li> <li>2. Consider the increasing use of digital therapeutics or "digiceuticals" in clinical treatment.</li> </ol>
<b>Longer-Term Opportunities</b>			
Electronic Patient-Reported Health Record Update Processes*	Transparency about the accuracy of patient data and consent to share it are lacking for patients, which in turn affects patient safety.	Better understand how requests for corrections, amendments, addenda, and deletions are processed and then disseminated, as well as the impact on the legal health record.	Hold a listening session to better understand the challenges and inform future standards for electronic patient-reported health record update processes for corrections, amendments, addenda, and deletions, including patients' and organizations' views.
Patient-Generated Health Data (PGHD)*	The use of PGHD may present liability concerns if inaccurate PGHD are used in clinical decisions or if the clinician chooses not to act based on the PGHD received.	Better understand the current state of clinicians' concerns about integrating electronic PGHD in treatment decisions.	Hold a listening session to assess progress on the integration of PGHD in electronic health records and clinical decisions and to identify remaining barriers.
Price/Cost Transparency*	Low compliance among hospitals with price/cost transparency rules, as well as non-user-friendly methods of sharing complex data, hinder patient access and use of price-related information.	Further understand patients' experience accessing and using price/cost transparency data.	Hold a listening session to learn about best practices for implementing price/cost transparency rules that enhance patients' experience accessing this data.

\*Topics that tend to recur across HITAC annual reports



## HITAC PROGRESS IN FY22

### 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 FY22

The HITAC's focus in FY22 was on developing interoperability standards priorities, reviewing the existing set of ONC-adopted standards, advancing electronic prior authorization, and continuing to evaluate the needs of public health data systems. The HITAC held 10 public meetings of the full committee, including a hearing on health equity, and 50 public meetings of the subcommittees. The HITAC delivered 135 recommendations and its annual report to the National Coordinator.

The full committee, through the work of several subcommittees, developed recommendations to support the work of the Office of the National Coordinator for Health IT (ONC). In FY22, the subcommittees included the:

- Adopted Standards Task Force 2022
- Annual Report Workgroup
- e-Prior Authorization Request for Information Task Force 2022
- Interoperability Standards Workgroup
- Public Health Data Systems Task Force 2022

The charges and accomplishments of the subcommittees are as follows:

#### Adopted Standards Task Force 2022

The Cures act requires the National Coordinator to convene interested parties to review the existing set of adopted standards and implementation specifications and make recommendations to either maintain them or phase them out. At the HITAC meeting on June 16, 2022, the HITAC formed the Adopted Standards Task Force 2022 to address the following charge from ONC:

- *Overarching Charge:* Review the existing set of ONC-adopted standards and implementation specifications and make recommendations to maintain or phase out such standards and implementation specifications, as required by 42 U.S. Code § 300jj-13 (*Setting Priorities for Standards Adoption*). The current set of ONC-adopted standards and implementation specifications is maintained on the [ONC Standards Hub](#).

#### Accomplishments in FY22

The Adopted Standards Task Force 2022 held nine public meetings in FY22. The HITAC approved and transmitted 55 recommendations to the National Coordinator in September 2022. The Task Force reviewed 55 ONC-adopted standards and then recommended a disposition status and a rationale for each standard. The Task Force recommended maintaining 14 standards as-is, maintaining or phasing out with replacement



four standards, and phasing out with replacement 37 standards. No standards were identified to be phased out entirely without a replacement.

### 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:**
  - 1) Analysis of HITAC progress related to the priority target areas
  - 2) Assessment of health IT infrastructure and advancements in the priority target areas
  - 3) Analysis of existing gaps in policies and resources for the priority target areas
  - 4) Ideas for potential HITAC activities to address the identified gaps

### Accomplishments in FY22

The Annual Report Workgroup held seven public meetings in FY22 to develop its recommendations. The HITAC approved the HITAC Annual Report for Fiscal Year 2021 (FY21) for submission to the National Coordinator in February 2022 and subsequent transmittal to the Secretary of HHS and to Congress. The HITAC Annual Report for FY21 reviews HITAC activities in FY21, describes the landscape of health IT infrastructure, identifies gaps and opportunities, and offers 23 recommendations for future HITAC activities.

### e-Prior Authorization Request for Information Task Force 2022

On January 24, 2022, ONC issued a request for information (RFI) titled [Request for information: Electronic Prior Authorization Standards, Implementation Specification, and Certification Criteria](#) that requested comments on how the ONC Health IT Certification Program could incorporate standards and certification criteria related to electronic prior authorization. At the HITAC meeting on January 19, 2022, ONC charged the HITAC with providing recommendations on ONC's RFI. The HITAC then formed the e-Prior Authorization Request for Information Task Force 2022 to address the following charge from ONC:

- **Overarching Charge:** Provide input and recommendations in response to the RFI on Electronic Prior Authorization to inform future rulemaking and other actions in this area.

### Accomplishments in FY22

The e-Prior Authorization Request for Information Task Force 2022 held seven public meetings in FY22. The HITAC approved and transmitted 13 recommendations to the National Coordinator in March 2022. The recommendations focus on the selection of health IT certification criteria and moving the healthcare industry toward streamlined, digitized electronic prior authorization processes with data-driven interoperability.



## Interoperability Standards Workgroup

The Cures Act requires the HITAC to set priorities for standards adoption. On January 13, 2022, ONC published its Draft USCDI Version 3 and the companion Health IT Standards Bulletin 2022-1 and sought public feedback on the data classes and elements included in this version. On January 19, 2022, as part of this public feedback process, ONC charged the HITAC with making specific recommendations on the draft content in USCDI Version 3. The HITAC then formed the Interoperability Standards Workgroup and charged it with the following.

- **Overarching Charge:** Review and provide recommendations on the Draft USCDI Version 3 and other interoperability standards.
- **Specific Charge:**
  - 1) Evaluate Draft USCDI v3 and provide HITAC with recommendations for:
    - 1a – New data classes and elements from Draft USCDI v3
    - 1b – Level 2 data classes and elements not included in Draft USCDI v3
  - 2) Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications

## Accomplishments in FY22

The Interoperability Standards Workgroup held 21 public meetings in FY22. The HITAC approved and transmitted 23 recommendations on Draft USCDI Version 3 to the National Coordinator in April 2022. These recommendations focused on whether new data classes and elements should be included in Draft USCDI Version 3. The HITAC approved and transmitted 21 recommendations on the ISA to the National Coordinator in June 2022. These recommendations focused on improving the process and structure of the ISA and identifying new use cases and standards to track.

## 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:**

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:

  1. 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.
  2. 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.



3. Recommend which data flows, aligned with existing (f) criteria, should be prioritized for standardized receipt of data.

### Accomplishments in FY22

The Public Health Data Systems Task Force 2022 held six public meetings in FY22. 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 FY22. However, work remains in these target areas to achieve the full potential of using health IT tools to help transform the healthcare sector. In FY23, ONC and the HITAC will continue to focus on advancing the implementation of the health IT provisions of the Cures Act including 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 FY22, 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 FY22

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

#### ONC Benchmarks in FY22

ONC Activity	FY22 Progress	FY23 Benchmarks
Health Equity by Design	<ul style="list-style-type: none"> <li>• Included new elements in USCDI Version 3 that address SDOH; SO/GI; and functional, disability, and mental/cognitive status</li> <li>• Released Project US@ Technical Specification Final Version 1.0.</li> <li>• Launched the ONC Public Health Informatics &amp; Technology (PHIT) Workforce Development Program with diverse awardees.</li> </ul>	<ul style="list-style-type: none"> <li>• Advance adoption and use of USCDI data classes and elements that support health equity.</li> <li>• Inform and support strategic federal activities focused on the alignment of interoperable, granular data on race and ethnicity with federal standards for the classification of this data.</li> <li>• Release Project US@ Technical Specification Version 2.0.</li> <li>• Train 4,000 students over a four-year period in public health informatics and technology through the PHIT Program.</li> </ul>
Standards	<p><i>USCDI</i></p> <ul style="list-style-type: none"> <li>• Published USCDI Version 3, which includes two new data classes and 24 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 4 with additional data classes and data elements.</li> </ul>
	<p><i>USCDI+</i></p> <ul style="list-style-type: none"> <li>• USCDI+ collaborations underway:                             <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> </li> </ul>	<p><i>USCDI+</i></p> <ul style="list-style-type: none"> <li>• With HRSA, work to align Uniform Data System (UDS) reporting with interoperability standards and transition to patient-level reporting requirements with the USCDI and other quality reporting efforts.</li> </ul>
	<p><i>Standards Version Advancement Process (SVAP)</i></p> <ul style="list-style-type: none"> <li>• Approved 10 standards.</li> <li>• Advanced SDOH and SO/GI data standards.</li> </ul>	<p><i>SVAP</i></p> <ul style="list-style-type: none"> <li>• Publish National Coordinator-approved updated versions of health IT standards and implementation specifications.</li> </ul>





ONC Activity	FY22 Progress	FY23 Benchmarks
	<p><b>HL7® FHIR®</b></p> <ul style="list-style-type: none"> <li>• TEFCA RCE, The Sequoia Project, released the FHIR® Roadmap for TEFCA Exchange.</li> <li>• The HL7® FHIR® at Scale Taskforce (FAST) became an official HL7® FHIR® Accelerator.</li> <li>• FHIRRedApp demonstrated a mobile- and web-based platform that uses FHIR® APIs and allows patients to access (and grant access) to their data “without special effort.”</li> <li>• HL7® US Realm contract supports annual updates to FHIR® US Core Implementation Guide following updates to the USCDI.</li> <li>• Two cooperative agreements with HL7® support: <ul style="list-style-type: none"> <li>○ FHIR® IG development (e.g., SDOH/Gravity, at-home testing, international patient summary, bulk data)</li> <li>○ FHIR® infrastructure (e.g., FHIR® IG publisher)</li> </ul> </li> <li>• FHIR® R5 published.</li> </ul>	<p><b>HL7® FHIR®</b></p> <ul style="list-style-type: none"> <li>• Support the release of HL7® FHIR®.</li> <li>• Continue annual updates to FHIR® US Core Implementation Guide to align with the USCDI.</li> </ul>
	<p><b>Public Health</b></p> <ul style="list-style-type: none"> <li>• Launched Helios initiative, jointly supported by the CDC and ONC, as HL7® FHIR® Accelerator.</li> <li>• Launched the USCDI+ Public Health initiative to identify data needs for public health beyond the USCDI.</li> </ul>	<p><b>Public Health</b></p> <ul style="list-style-type: none"> <li>• Continue to support the Helios Initiative.</li> <li>• Incorporate USCDI+ into standards development organization (SDO) activities and FHIR® profile development.</li> <li>• Identify new opportunities to advance FHIR® through the use of public health grant language.</li> </ul>
	<p><b>HHS-Wide Approach on Health IT Standards Investments</b></p> <ul style="list-style-type: none"> <li>• ONC directed to establish and oversee a consistent department-wide approach to incorporate standard health IT requirements language in applicable funding programs and provide assistance to agencies.</li> </ul>	<p><b>HHS-Wide Approach for Health IT Standards Investments</b></p> <ul style="list-style-type: none"> <li>• Incorporate standard health IT requirements language in applicable HHS funding programs, contracts, and policies.</li> <li>• Assist HHS agencies to maximize the use of HHS-approved standards.</li> </ul>



ONC Activity	FY22 Progress	FY23 Benchmarks
Certification	<p><i>Certification Program Requirements</i></p> <ul style="list-style-type: none"> <li>• Developers attested to progress in meeting the Conditions and Maintenance of Certification.</li> <li>• All certified health IT developers subject to Real-World Testing submitted their first testing plans.</li> </ul>	<p><i>Certification Program Requirements</i></p> <ul style="list-style-type: none"> <li>• By December 31, 2022, certified health IT developers must update and provide technology that meets the ONC Cures Act Final Rule criteria.</li> </ul>
	<p><i>Certification Testing</i></p> <ul style="list-style-type: none"> <li>• Released Inferno 2.0 and launched the Inferno Framework.</li> <li>• Launched the §170.315(g)(10) Standardized API Test Kit.</li> </ul>	<p><i>Certification Testing</i></p> <ul style="list-style-type: none"> <li>• By March 15, 2023, Real-World Testing results from certified health IT developers are published on the CHPL.</li> </ul>
Exchange	<p><i>TEFCA</i></p> <ul style="list-style-type: none"> <li>• The RCE released 10+ TEFCA Standard Operating Procedures (SOPs) for Exchange Purposes.</li> <li>• The RCE engaged over 4,700 individuals through 21 engagement events from September 2021 through August 2022.</li> </ul>	<p><i>TEFCA</i></p> <ul style="list-style-type: none"> <li>• The RCE enters the operational phase of TEFCA.                             <ul style="list-style-type: none"> <li>○ QHINs selection, onboarding, and sharing begins.</li> <li>○ Additional SOPs are released.</li> </ul> </li> </ul>
	<p><i>Information Blocking</i></p> <ul style="list-style-type: none"> <li>• Regulations went into effect for all applicable actors as of April 5, 2021.</li> <li>• ONC received 539 submissions through the ONC Report Information Blocking Portal as of November 4, 2022.</li> </ul>	<p><i>Information Blocking</i></p> <ul style="list-style-type: none"> <li>• Beginning October 6, 2022, the definition of EHI is no longer limited to the elements represented in the USCDI Version 1.</li> <li>• ONC conducts ongoing education and outreach that invite the public to interact with policy experts.</li> </ul>



## FY22 HITAC Member list

- Aaron Miri, Co-Chair, Baptist Health\*
- Denise Webb, Co-Chair, Individual
- Medell Briggs-Malonson, Member, UCLA Health\*
- Hans Buitendijk, Member, Oracle Cerner
- Steven (Ike) Eichner, Texas Department of State Health Services
- Cynthia A. Fisher, Member, Patient Rights Advocate
- Lisa Frey, Member, St. Elizabeth Healthcare
- Rajesh Godavarthi, Member, MCG Health, part of the Hearst Health network
- Valerie Grey, Member, State University of New York
- Steven Hester, Member, Norton Healthcare
- Jim Jirjis, Member, HCA Healthcare\*
- John Kansky, Member, Indiana Health Information Exchange
- Kensaku Kawamoto, Member, University of Utah Health
- Steven Lane, Member, Health Gorilla\*
- Leslie Lenert, Member, Medical University of South Carolina
- Hung S. Luu, Member, Children's Health
- Arien Malec, Member, Change Healthcare
- Clem McDonald, Member, National Library of Medicine
- Aaron Neinstein, Member, USCF Health
- Eliel Oliveira, Member, Dell Medical School, University of Texas at Austin\*
- Brett Oliver, Member, Baptist Health\*
- James Pantelas, Member, Individual
- Raj Ratwani, Member, MedStar Health
- Abby Sears, Member, OCHIN
- Alexis Snyder, Member, Individual
- Fillipe Southerland, Member, Yardi Systems, Inc.
- Sheryl Turney, Member, Elevance Health
- Thomas Cantilina, Federal Representative, Defense Health Agency, Department of Defense
- Adi V. Gundlapalli, Federal Representative, Centers for Disease Control and Prevention
- Ram Iyer, Federal Representative, Food and Drug Administration
- Jonathan Nebeker, Federal Representative, Department of Veterans Health Affairs
- Michelle Schreiber, Federal Representative, Centers for Medicare and Medicaid Services
- Ram Sriram, Federal Representative, National Institute of Standards and Technology
- Nara Um, Federal Representative, Federal Electronic Health Record Modernization (FEHRM)

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- Kory Mertz
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