



Draft Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019

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Executive Summary

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 U.S. Department of Health and Human Services (HHS) and to Congress each fiscal year. This report complies with that directive by reviewing fiscal year 2019 (FY19) HITAC activities, describing the landscape of health information technology (IT) infrastructure across priority target areas, analyzing infrastructure gaps, and offering recommendations for future HITAC activities.

HITAC Progress in FY19

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

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) required by the Cures Act. The subcommittees included the:

- Annual Report Workgroup
- Conditions and Maintenance of Certification Requirements Task Force
- Health IT for the Care Continuum Task Force
- Information Blocking Task Force
- Interoperability Standards Priorities Task Force
- NPRM U.S. Core Data for Interoperability Task Force
- Trusted Exchange Framework and Common Agreement Task Force

Health IT Infrastructure Landscape

The Cures Act specifies three priority target areas within which the HITAC should focus its activities: interoperability, privacy and security, and patient access to information. These priority target areas are an organizing principle for classifying the HITAC's work and organizing this report.

Federal Activities across the Priority Target Areas

In FY19, there were considerable health IT advancements throughout various agencies of the federal government. ONC released a proposed rule to implement provisions in Title IV of the Cures Act, called the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Notice of Proposed Rulemaking ([Cures Act NPRM](#)). ONC also released the [second draft](#) of the Trusted Exchange Framework and Common Agreement (TEFCA) and selected the [Recognized Coordinating Entity \(RCE\)](#). The Centers for Medicare & Medicaid Services (CMS) released a [proposed rule](#) to improve interoperability and expand patients' access to their health information. There were several other federal activities that affect the HITAC's priority target areas, including the Department of Defense (DoD) and Department of Veterans Affairs (VA) electronic health records (EHR) modernization effort, the National Institutes of Health (NIH) [All of Us Research Program](#), and a collaboration between ONC and CMS to reduce [clinician burden](#) related to the use of health IT.

Priority Target Area: Interoperability

While most healthcare providers now use EHRs, interoperability remains fragmented and a variety of barriers must be addressed. Incorporating data received from outside sources, increasing price transparency, integrating data from devices, and using more clinical data for research purposes are key opportunities. Using health IT to respond to the opioid crisis, accurately matching patients across organizations, integrating social determinants of health data, tracking adverse patient safety events, and attending to the needs of additional care settings and stakeholder groups are also essential to the success of the nation's health IT infrastructure. The HITAC is working to identify priority uses of health IT and the associated standards and implementation specifications that support such uses.

Priority Target Area: Privacy and Security

Privacy and security of health data are important considerations in advancing and maintaining trust in interoperability. Data generated or stored outside of the Health Insurance Portability and Accountability Act (HIPAA) framework are growing, and patients are often unaware that some of their health information is not protected by HIPAA. The varying requirements of international, federal, and state privacy laws continue to present challenges. New technological capabilities that can re-identify de-identified data and poor privacy and security practices both heighten the vulnerability of patient information stored in health information systems and on devices and may lead to inappropriate care or patient harm.

Priority Target Area: Patient Access to Information

Access to health IT can have a positive impact on health, healthcare, and health equity by supporting shared decision-making between patients and providers, providing personalized self-management tools, and delivering accurate, accessible, and actionable health information. Continued information and education, improved accessibility, and increased use of application programming interfaces (APIs) and patient-generated health data (PGHD) are needed to increase both patients' and providers' awareness of the benefits of the use of data and health IT resources.

Emerging Issues across the Priority Target Areas

The Annual Report Workgroup identified multiple emerging issues that will be of growing importance to the deliberations of the HITAC moving forward. This includes issues such as integration of health data from the Internet of Things (IoT), prescription of digital apps, linking genetic data to social behavior, machine learning in healthcare, and sharing diagnostic imaging. These issues will continue to be closely tracked by the Annual Report Workgroup for consideration in future reports.

Health IT Infrastructure Gaps, Opportunities, and Recommendations

The Cures Act requires an analysis identifying existing gaps in policies and resources for achieving the ONC FY19 objectives and benchmarks and furthering interoperability throughout the health IT infrastructure, as well as recommendations for addressing the gaps identified. The HITAC has focused on the following key gaps and opportunities for the health IT industry and has recommended related HITAC activities.

The following table summarizes the HITAC's assessment. Within each priority 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, while longer-term opportunities are anticipated to begin in three or more years.

Key Gaps	Key Opportunities	Recommended HITAC Activities
Priority Target Area: Interoperability		
Immediate Opportunities		
Challenges with incorporation and reconciliation of data received from outside sources	Enable easier integration and use of data received from outside sources	Review and make recommendations on best practices for how health IT developers and providers can integrate and use data received from outside sources, including addressing data accuracy
Lack of price transparency	Offer guidance about the role of health IT in improving price transparency	Offer ideas for the role of health IT in improving price transparency of healthcare services
Limited unique device identifier (UDI) integration	Increase understanding of the challenges of integration of UDI data	Convene a hearing to understand trends related to UDI data integration and understand the effect on various workflows (e.g., clinical, administrative, research, and patient)
Need for clarification on the use of health data made available electronically for research purposes	Establish a framework for the use of health data made available electronically for research purposes	Review and make recommendations about ONC's role in setting guidelines for the use of health data made available electronically for research purposes
Longer-Term Opportunities		
Limited EHR integration with Prescription Drug Monitoring Programs (PDMPs)	Improve and accelerate the use of health IT to respond to the opioid crisis	<ol style="list-style-type: none"> Encourage the adoption of standards to support data segmentation by identifying policy needs and functional requirements to address patient privacy and provider needs Identify opportunities to use TEFCA to enable the exchange of data necessary to support the response to the opioid crisis
Need for improved patient matching when sharing data	Improve patient matching	Hold hearings to explore how new and emerging technology, such as machine learning and referential matching, are improving patient matching, and develop recommendations to inform ONC's patient matching strategy in light of the findings
Nascent capture and use of social determinants of health (SDOH) data	Develop and adopt standards for SDOH data collection, transfer, and integration for population health and individuals' needs	<ol style="list-style-type: none"> Continue to review and recommend SDOH data elements for inclusion in the United States Core Data for Interoperability (USCDI) framework and promote continued SDOH standards development Review opportunities for HHS to require the use of standardized psychological, social, and behavioral data across agency programs
EHR-related adverse patient safety events	Increase transparency of EHR-related adverse patient safety events	Develop recommendations on ways ONC can include EHR-related patient safety events in the EHR Reporting Program
Unmet needs of additional care settings and stakeholder groups	Improve the electronic data exchange capabilities of behavioral health and long-term care providers	Review and recommend steps for ONC to improve the ability of behavioral health and long-term care providers to electronically exchange data

Key Gaps	Key Opportunities	Recommended HITAC Activities
Priority Target Area: Privacy and Security		
Immediate Opportunities		
Lack of clear rules for data not subject to HIPAA privacy protections	Increase transparency and patient education for business practices and other potential uses not covered under HIPAA	<ol style="list-style-type: none"> (1) Convene a HITAC workgroup to review and provide recommendations about federal agencies' activities addressing third-party access to health data (2) Identify educational approaches, technological mitigators, and potential regulatory solutions that offer improved transparency of privacy protections outside the purview of HIPAA (3) Develop recommendations for additional steps for HHS and industry to take to enhance education about the requirements and applicability of HIPAA, Title 42 of the Code of Regulations, Part 2: Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2), and the Family Educational Rights and Privacy Act (FERPA) (4) Help ONC identify and define policy needs and functional requirements for data segmentation for patients, providers, and other stakeholders
Lack of control over sharing and disclosure of information	Improve the capabilities of health IT to electronically capture, store, and share consent information	Identify and suggest how consent should be captured under TEFCFA
	Facilitate more exchange of SDOH data between healthcare providers and community service organizations and more patient education about consent	Review the consent policies and data use agreements of early adopters of SDOH data exchange (i.e., health information exchanges (HIEs), community information exchanges (CIEs)) to develop best practices for other healthcare entities looking to exchange SDOH data
	Identify emerging concerns related to provider-directed and patient-managed PGHD creation and use	Review actions already underway regarding the management of and processes for protecting the privacy and security of PGHD
Lack of clarity on the effect of international regulations on U.S. healthcare data exchange and access	Increase knowledge of the impact of international regulations affecting the U.S. healthcare system	Identify educational approaches that offer increased transparency for international regulations (such as the General Data Protection Regulation (GDPR)) that affect the U.S. healthcare system
Longer-Term Opportunities		
Variability of information-sharing policies across states	Increase the alignment of data sharing policies across states	<ol style="list-style-type: none"> (1) Review and make recommendations about the federal role in setting guidelines across states for the exchange of data (2) Collaborate with the National Committee on Vital and Health Statistics (NCVHS) on its proposed revisions to HIPAA to consider strategies for aligning policies across states

Key Gaps	Key Opportunities	Recommended HITAC Activities
New technological capabilities to re-identify de-identified data	Increase awareness of technological capabilities to re-identify de-identified data	<ol style="list-style-type: none"> (1) Identify additional steps HHS should take to raise awareness about how de-identified data are used today and about the ability of new technological capabilities to re-identify de-identified data (2) Convene a listening session to assess the development of technologies that prevent re-identification
Challenges in the adoption of cybersecurity framework(s)	Offer guidance to the healthcare sector on ways to improve cybersecurity preparedness	<ol style="list-style-type: none"> (1) Review existing ONC cybersecurity educational resources to identify any necessary updates, revisions, or new materials that should be developed (2) Hold a hearing to identify additional opportunities for the HITAC to help improve cybersecurity preparedness
Priority Target Area: Patient Access to Information		
Immediate Opportunities		
Limited accessibility and usability of patient portals (and other patient-facing technology)	Consider improvement to the accessibility and usability of patient portals (and other patient-facing technology)	Assess patient portals' and patient-facing mobile apps' operational effectiveness, patient engagement, and/or patient understanding and use of data to establish measures in the future
Access to patient data remains highly fragmented from the patients' perspective	Develop an updated roadmap for patient engagement and access to data that is less dependent on providers and their EHR developers	Hold listening sessions of experts and representatives of stakeholder groups (including federal agencies) to identify ideas for an updated roadmap for patient access
Ensuring compliance around API use	Track deployment of APIs certified to the 2015 Edition to identify gaps in API trust frameworks and offer guidance to developers and providers as needed	<ol style="list-style-type: none"> (1) Assess deployment of 2015 Edition Certified EHR Technology (CEHRT) in the field to identify any early gaps in existing API trust frameworks and HHS Office for Civil Rights (OCR) guidelines and develop recommendations on how to fill the gaps. Identified challenges should be analyzed to determine if the policies proposed in the Cures Act NPRM will address the issue and if additional action or guidance is required (2) Suggest ideas for guidance by HHS on API use
Longer-Term Opportunities		
Barriers to use and sharing of PGHD	Further understand patients' experience of sharing health data with their care team and providers' business reasons and technical ability to use and share PGHD	Explore patient and provider experiences with sharing and using PGHD to continue to identify best practices and gaps

Foreword

We are pleased to present the annual report of the Health Information Technology Advisory Committee (HITAC) for FY19.

This report describes the work undertaken by the HITAC during its second year. The HITAC was formed by the 21st Century 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 committee focused its evaluation in three priority target areas: interoperability, privacy and security, and patient access to Information. In FY19, a large part of the HITAC's work was to analyze, review, and comment on the Cures Act NPRM. We created several subcommittees that presented their work to the HITAC full committee for review and approval. In June 2019, the HITAC submitted over 250 pages of comments and 144 recommendations on the Cures Act NPRM to the National Coordinator over our signatures. In addition, this report highlights the work done by the HITAC's Trusted Exchange Framework Task Force, the U.S. Core Data for Interoperability Task Force, and the Interoperability Standards Priorities Task Force. These subcommittees were formed to address particular initiatives identified by Congress as health IT priorities for ONC. During the year, the HITAC also collaborated with NCVHS, for example, through a joint hearing on prior authorization and administrative simplification. Several areas for future HITAC work were surfaced during the HITAC meetings in FY19, and robust discussion among the members yielded several areas for potential activity in FY20 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 is our privilege to serve as co-chairs for the HITAC. 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 use of better information and technology to improve care delivery and the health and well-being of everyone in the United States.

Carolyn Petersen and Robert Wah
Co-Chairs, Health Information Technology Advisory Committee

Overview

Legislative Requirements

In December 2016, Congress passed the Cures Act, P.L. 114-255, with a bipartisan majority. The Cures Act created the HITAC, which is governed by the provisions of the Federal Advisory Committee Act (FACA), P.L. 92-463, as amended, 5 U.S.C. App. 2. The HITAC makes recommendations to the National Coordinator for Health IT about 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.

The Cures Act requires the HITAC to develop an Annual Report to be submitted to the Secretary of HHS and Congress each fiscal year (FY). The annual report must provide:

- Analysis of HITAC progress related to priority target areas;
- Assessment of health IT infrastructure and advancements in the priority target areas;
- Analysis of existing gaps in policies and resources for the priority target areas; and
- Ideas for potential HITAC activities to address the identified gaps.

HITAC Priority Target Areas

Section 4003(e) of the Cures Act established the following priority target areas for the HITAC:

- **Interoperability** - “Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.”
- **Privacy and Security of Health Information** - “The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and healthcare operations (as such terms are defined for purposes of the regulation promulgated under section 264(c) of HIPAA), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.”
- **Patient Access to Information** - “The facilitation of secure access by an individual to such individual’s protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age-related and other disability, cognitive impairment, or dementia.”
- **Any other target area** related to the above target areas that the HITAC identifies as an appropriate target area to be considered.

In FY19, the HITAC did not identify a need for additional target areas as defined in the Cures Act. The HITAC will revisit this consideration in the FY 2020 (FY20) annual report.

FY19 ONC Objectives and Benchmarks for the HITAC

As required by the Cures Act, ONC established a set of objectives and benchmarks to advance and measure the advancement of the priority target areas during FY19 and FY20, outlined below.

ONC Objectives in FY19-20

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

ONC Benchmarks in FY19-20

ONC Activity	ONC Benchmark*	Progress in Meeting in FY19
Publish final rule covering secure, standards-based APIs for patients to access their medical records and information blocking exceptions	Final rule published	<ul style="list-style-type: none"> • The Cures Act NPRM was published on March 4, 2019 • The HITAC submitted recommendations on the Cures Act NPRM to the National Coordinator for Health IT on June 3, 2019 • Final rulemaking is underway
Publish TEFCA	<ul style="list-style-type: none"> • RCE cooperative agreement awarded • Final Trusted Exchange Framework published • Draft Common Agreement made available for public comment 	<ul style="list-style-type: none"> • ONC published the first draft of TEFCA on January 5, 2018, and the second draft on April 19, 2019, for public comment • The HITAC submitted recommendations to the National Coordinator for Health IT on TEFCA Draft 2 on July 11, 2019 • ONC awarded the cooperative agreement for the RCE on September 3, 2019
Coordinate health IT standards and certification to support interoperability	<ul style="list-style-type: none"> • The HITAC final report on priority uses of health IT and associated standards and implementation specifications transmitted to the National Coordinator for Health IT • The HITAC recommendations on the U.S. Core Data for Interoperability (USCDI) Data Element Promotion Model transmitted to the National Coordinator for Health IT • Health Level Seven (HL7®) published Fast Healthcare Interoperability Resources (FHIR®) Release 4 (R4), updated US Core Profiles for R4, and a Bulk Data Access Implementation Guide 	<ul style="list-style-type: none"> • The HITAC Interoperability Standards Priorities Task Force addressed three Priority Use Cases (Orders & Results, Closed Loop Referrals & Care Coordination, and Medication & Pharmacy Data) with detailed recommendations included in the final report • The HITAC transmitted recommendations to the National Coordinator for Health IT for version 1 of the USCDI on April 18, 2018

* For both FY 2018 (FY18) and FY19, ONC has defined the HITAC benchmarks as standalone measures rather than comparisons to an established industry standard of excellence. Infrastructure advancements compared to a baseline will be assessed in future annual reports.

HITAC Progress in FY19

HITAC Task Force/Workgroup Meetings and Recommendations

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

Overall Accomplishments in FY19

The HITAC's focus in FY19 was on reviewing and developing recommendations on the Cures Act NPRM, TEFCA Draft 2, the USCDI Data Element Promotion Model, and priority uses of health IT and the associated standards and implementation specifications that support such uses. There were 120 public meetings held by the HITAC workgroup and task forces and 11 public meetings held by the HITAC. The HITAC delivered 172 recommendations to the National Coordinator for Health IT. HITAC also collaborated with NCVHS, for example, through a joint hearing on prior authorization and administrative simplification.

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 and charged it with the following:

- *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 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 FY19

The Annual Report Workgroup held 10 public meetings in FY19 to develop its recommendations. The HITAC approved the HITAC Annual Report for FY 2018 for submission to the National Coordinator for Health IT in April 2019 and subsequent transmittal to the Secretary of HHS and Congress. The HITAC Annual Report reviewed HITAC activities in FY18, described the landscape of health IT infrastructure, identified gaps and opportunities, and offered recommendations for future HITAC activities.

Conditions and Maintenance of Certification Requirements Task Force

At the HITAC meeting on February 20, 2019, ONC charged the HITAC with developing recommendations to inform the development of the final Cures rule. The HITAC then formed the Conditions and Maintenance of Certification Requirements Task Force and charged it with the following:

- *Overarching Charge:* Provide recommendations on the API, “real-world testing,” and “attestations” conditions and maintenance of certification requirements; updates to most 2015 Edition health IT certification criteria; changes to the ONC Health IT Certification Program; and deregulatory actions.
- *Specific Charge:* Provide recommendations on the following topics:
 1. “API,” “real-world testing,” and “attestations” conditions and maintenance of certification requirements
 2. Updates to the 2015 Edition certification criteria: “Standardized API for patient and population services,” “electronic health information export,” “electronic prescribing,” “clinical quality measures – export,” and privacy and security-related attestation criteria (“encrypt authentication credentials” and “multi-factor authentication”)
 3. Modifications to the ONC Health IT Certification Program (Program)
 4. Deregulatory actions related to certification criteria and Program requirements

Accomplishments in FY19

The Conditions and Maintenance of Certification Requirements Task Force held 18 public meetings in FY19 to develop its recommendations. The HITAC approved and transmitted [36 recommendations](#) to the National Coordinator for Health IT in June 2019.

The recommendations address the API, real-world testing, and attestation Conditions and Maintenance of Certification requirements. The HITAC recommended that ONC introduce a new edition of certification rather than propose changes to the current 2015 Edition. The HITAC suggested the real-world testing requirements should be clarified by ONC in several areas including what must be included in the test plan, the methodology required in the testing, and what must be measured. The HITAC recommended that ONC adopt HL7® FHIR® R4, provide additional time to implement bulk API queries, and further clarify the requirements and expectations regarding app registration. The HITAC also recommended several revisions to the proposed updates to the 2015 Edition certification criteria.

Health IT for the Care Continuum Task Force

At the HITAC meeting on February 20, 2019, ONC charged the HITAC with developing recommendations to inform the development of the final Cures Act rule. The HITAC then formed the Health IT for the Care Continuum Task Force and charged it with the following:

- *Overarching Charge:* Provide recommendations on ONC’s approach, recommendations, and identified 2015 Edition certification criteria to support pediatric care and practice settings; related criteria to support multiple care and practice settings; and a request for information on how health IT can support the treatment and prevention of opioid use disorder.
- *Specific Charge:* Provide recommendations on the following topics:
 1. The 10 ONC recommendations to support the voluntary certification of health IT for pediatric care, including whether to remove a recommendation
 2. Identified 2015 Edition certification criteria for supporting the certification of health IT for pediatric care and practice settings
 3. Pediatric technical worksheets
 4. 2015 Edition Data Segmentation for Privacy (“DS4P”) and “consent management for APIs” certification criteria
 5. How health IT can support the treatment and prevention of opioid use disorder in alignment with the HHS strategy to address the opioid crisis

Accomplishments in FY19

The Health IT for the Care Continuum Task Force held 11 public meetings in FY19 to develop its recommendations. The HITAC approved and transmitted [16 recommendations](#) to the National Coordinator for Health IT in June 2019.

The recommendations address health IT supporting pediatric care and practice settings; data segmentation for privacy; and how health IT can support the treatment and prevention of opioid use disorder (OUD). The HITAC recommended retaining the 10 ONC Pediatric Health IT Recommendations for the voluntary certification of health IT for pediatric care and affirmed the existing and proposed certification criteria as relevant for the voluntary certification of health IT for pediatric care. The HITAC recommended several future actions ONC should take to address OUD, such as reducing the burden to access medication history by making PDMPs the single point of entry for this data. The HITAC recommended that ONC establish a multi-stakeholder workgroup to identify and define policy needs and functional requirements to address and balance patients' desires to restrict data to only what must be transmitted to support safe coordinated care.

Information Blocking Task Force

At the HITAC meeting on February 20, 2019, ONC charged the HITAC with developing recommendations to inform the development of the final Cures Act rule. The HITAC then formed the Information Blocking Task Force and charged it with the following:

- *Overarching Charge:* Provide recommendations on policies related to information blocking; the “information blocking,” “assurances,” and “communications” conditions and maintenance of certification requirements; and the enforcement of all the conditions and maintenance of certification requirements.
- *Specific Charge:* Provide recommendations on the following topics:
 1. Information Blocking:
 - a. ONC definitions/interpretations of certain statutory terms and provisions, including the price information request for information
 - b. Seven exceptions to the information blocking definition, and any additional exceptions (request for information)
 - c. Complaint process
 - d. Disincentives for healthcare providers (request for information)
 2. “Information blocking,” “assurances,” and “communications” conditions and maintenance of certification requirements
 3. Enforcement of all the conditions and maintenance of certification requirements

Accomplishments in FY19

The Information Blocking Task Force held 32 public meetings in FY19 to develop its recommendations. The HITAC approved and transmitted [60 recommendations](#) to the National Coordinator for Health IT in June 2019.

The recommendations address the information blocking provisions of the Cures Act NPRM. The HITAC recommended revisions to definitions of key terms to ensure that the appropriate scope of actors and actions will be covered by information blocking. The HITAC concurred with the inclusion of price information in the definition of electronic health information (EHI) to support price transparency and

encouraged ONC to take additional steps to strengthen the proposal. The HITAC recommended several revisions and refinement to the seven proposed exceptions to information blocking to promote clarity and simplicity while reflecting the intent of Congress in the Cures Act. The HITAC also recommended revisions to the assurances and communications Conditions and Maintenance of Certification requirements.

Interoperability Standards Priorities Task Force

The Cures Act requires the HITAC to set priorities for standards adoption. At the HITAC meeting on June 20, 2018, ONC charged the HITAC with providing recommendations to the National Coordinator for Health IT on standards priorities. The HITAC then formed the Interoperability Standards Priorities Task Force and charged the Task Force with the following:

- *Overarching Charge:* To make recommendations on priority uses of health information technology and the associated standards and implementation specifications that support such uses.
- *Specific Charge:*
 1. Make recommendations on the following:
 - a. Priority uses of health IT (consistent with the Cures Act’s identified priorities)
 - b. The standards and implementation specifications that best support or may need to be developed for each identified priority; and
 - c. Subsequent steps for industry and government action
 2. Publish a report summarizing its findings

Accomplishments in FY19

The Interoperability Standards Priorities Task Force held 17 public meetings in FY19, and it is expected that it will finalize its initial set of recommendations and final report in FY20.

NPRM U.S. Core Data for Interoperability Task Force

At the HITAC meeting on February 20, 2019, ONC charged the HITAC with developing recommendations to inform the development of the final Cures Act rule. The HITAC then formed the NPRM U.S. Core Data for Interoperability Task Force and charged it with the following:

- *Overarching Charge for Phase 1:* Review the newly specified data elements proposed in USCDI v1
- *Specific Charge:* Provide recommendations on the following:
 1. Inclusion of Provenance Data Elements
 2. Inclusion of Clinical Notes Data Elements
 3. Inclusion of Pediatric Vital Signs Data Elements
 4. Inclusion of Address and Phone Number Data Elements
 5. Missing Data Elements within the Data Classes
- *Overarching Charge for Phase 2:* Provide recommendations for the USCDI Data Element Promotion Model
- *Specific Charge:* Provide recommendations on the following:
 1. Promotion Model Lifecycle for Submitted Data Elements
 2. Data Element Submission Information
 3. Data Element Promotion Criteria

Accomplishments in FY19

The NPRM U.S. Core Data for Interoperability Task Force held 17 public meetings in FY19 to develop its recommendations. The HITAC approved and transmitted [32 recommendations](#) to the National Coordinator for Health IT in June 2019.

The recommendations address whether to include, revise, omit or add specific data elements to the USCDI version 1. The HITAC generally agreed with the proposed additions to the USCDI and recommended several revisions to the data elements. The HITAC recommended adding data elements to the USCDI version 1 in the following data classes: Patient Demographics, Provenance, the Care Team Members, and Clinical Notes. The HITAC also recommended initiating the development of a Quality Measures data class for inclusion in a subsequent version of the USCDI.

Trusted Exchange Framework and Common Agreement Task Force

At the HITAC meeting on April 25, 2019, ONC charged the HITAC with developing recommendations to inform the development of the final Common Agreement. The HITAC charged the Trusted Exchange Framework and Common Agreement Task Force with the following:

- *Overarching Charge:* The Trusted Exchange Framework and Common Agreement Task Force will develop and advance recommendations on the TEFCA Draft 2 to inform the development of the final Common Agreement.
- *Specific Charge:* Make specific recommendations on the Minimum Required Terms and Conditions and the Qualified Health Information Network (QHIN) Technical Framework (QTF):
 1. Definition, Structure, and Application Process for QHINs: Recommendations for further clarifying the eligibility requirements and application process for becoming a QHIN.
 2. Exchange Purposes and Modalities: Recommendations on enhancing or clarifying the seven (7) exchange purposes and three (3) exchange modalities proposed in the MRTCs, as well as provisions regarding EHI reciprocity and permitted and future uses of EHI.
 3. Privacy: Recommendations on privacy requirements for participating entities, including Meaningful Choice, Written Privacy Summary, Summary of Disclosures, and Breach Notifications
 4. Security: Recommendations on security requirements for participating entities, including minimum security requirements, identity proofing, authorization, and authentication.

Accomplishments in FY19

The Trusted Exchange Framework and Common Agreement Task Force held 15 public meetings in FY19 to develop its recommendations. The HITAC approved and transmitted [28 recommendations](#) to the National Coordinator for Health IT in July 2019.

The recommendations address the proposals in TEFCA Draft 2. To ensure adoption and use of TEFCA, the HITAC recommended that ONC ensure future versions complement existing frameworks and networks and incentivize participation. The HITAC recommended that ONC outline functional requirements sufficient to meet the policy goals of TEFCA and avoid, whenever possible, identifying specific technical solutions. The HITAC strongly endorsed the focus on the needs of patients in TEFCA, including the expansion of patients' right to access records to include all TEFCA participating entities, and encouraged ONC to clarify the functional requirements of the Individual Access Services Exchange Purpose.



Health IT Infrastructure Landscape Analysis

Federal Activities across the Priority Target Areas

ONC's key responsibilities include formulating the federal government's health IT strategy and promoting coordination of federal health IT policies, technology standards, and programmatic investments. ONC helps coordinate health IT initiatives across HHS programs and other relevant executive branch agencies to avoid duplication of effort and to ensure that each agency undertakes activities primarily within the areas of its greatest expertise and technical capability. This section describes the health IT activities advanced by various agencies of the federal government during FY19. Certain key federal activities that the HITAC considered to be cross-cutting across the priority target areas have been included in this section. It does not encapsulate all relevant federal activities conducted throughout FY19; some of them are addressed within priority target area sections throughout this report.

ONC's Regulation for the 21st Century Cures Act

On March 4, 2019, the Cures Act NPRM was published in the Federal Register. The Cures Act NPRM implements provisions in Title IV of the Cures Act. The Cures Act NPRM aims to increase innovation and competition by enabling more choice in care and treatment and by giving patients and their healthcare providers secure access to health information and new tools.

The following sections summarize key provisions of the Cures Act NPRM for which ONC requested input from the HITAC.

Information Blocking

The Cures Act defines information blocking and authorizes the Secretary of HHS to identify reasonable and necessary activities that do not constitute information blocking. In the Cures Act NPRM, ONC identifies several reasonable and necessary activities as exceptions to the information blocking definition, provided certain conditions are met. These categories were developed using feedback from stakeholders and in consultation with appropriate federal agencies. If the actions of a regulated actor (healthcare provider, health IT developer, or HIE or network) satisfy one or more exceptions, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.

There is a wide variety of perspectives on the types of business models that may create barriers to interoperability. Some health IT developers and health information networks (HINs) have adopted pricing practices that are rent-seeking, opportunistic, or exclusionary and thus interfere with the access, exchange, and use of data. For instance, some actors are perceived as charging rates designed to deter connectivity or exchange with competing technologies or services. Under the proposed rule, actors could be found to be information blocking if they pursue such pricing practices and the practices do not fall within the definition of an exception.

Revised and New Certification Criteria, and Conditions and Maintenance of Certification

In the Cures Act NPRM, ONC proposes additions and changes to the ONC Health IT Certification Program. ONC proposes to implement provisions of the Cures Act, including Conditions and Maintenance of Certification requirements for health IT developers and the voluntary certification of health IT for use by

pediatric healthcare providers. ONC also proposes to modify the 2015 Edition by adding, revising, and removing certification criteria.

More specifically, ONC proposes Conditions and Maintenance of Certification requirements related to (1) information blocking; (2) assurances; (3) communications; (4) APIs; (5) real-world testing of certified health IT; and (6) attestations. ONC proposes an enforcement approach to encourage consistent compliance with the requirements. The Cures Act NPRM outlines a corrective action process for ONC to use when there are potential or known instances where a health IT developer is not meeting a Condition or Maintenance of Certification requirement under the ONC Health IT Certification Program. The Conditions and Maintenance of Certification can cover both the actions of the developer that offers a certified product and the actual certified product. For example, if a health IT developer with multiple products has a single product certified, the information blocking prohibitions apply to all its non-certified products as well.

Application Programming Interfaces

The Cures Act calls on health IT developers to publish APIs and allow health information to be accessed, exchanged, and used without special effort using APIs or successor technology or standards, as provided for under applicable law. The Cures Act NPRM seeks to support patients' secure and seamless access to their EHI through APIs and apps. ONC proposes certification requirements that would improve interoperability by focusing on standardized, transparent, and pro-competitive API practices. This approach is intended to further support the access, exchange, and use of EHI by patients and providers.

United States Core Data for Interoperability (USCDI)

To assist in the move towards value-based care, ONC proposes in the Cures Act NPRM to replace the Common Clinical Data Set (CCDS) reference in the 2015 Edition with a broader data set referred to as the USCDI. The proposed USCDI includes all the information required in the CCDS, in addition to new required data classes and data elements. This will increase the minimum baseline of data that must be commonly available for interoperable exchange (see Figure 1). If adopted, health IT developers will need to update their certified health IT to support the USCDI for all affected certification criteria. ONC intends to establish and follow a predictable, transparent, and collaborative process to expand the USCDI. This includes providing stakeholders the opportunity to comment on its expansion. The USCDI establishes a priority set of standardized data elements that will be broadly required to be available in certified health IT modules. In contrast, EHI establishes a broad and far-reaching set of data elements that are covered by information blocking. A subset of the EHI data elements is included in the USCDI, some data elements have one or more applicable standards, and other data elements have no standard(s).

Figure 1: Proposed USCDI Version 1¹

Assessment and Plan of Treatment 	Laboratory <ul style="list-style-type: none"> • Tests • Values/Results 	Provenance *NEW <ul style="list-style-type: none"> • Author • Author Time Stamp • Author Organization
Care Team Members 	Medications <ul style="list-style-type: none"> • Medications • Medication Allergies 	Smoking Status
Clinical Notes *NEW <ul style="list-style-type: none"> • Consultation Note • Discharge Summary Note • History & Physical • Imaging Narrative • Laboratory Report Narrative • Pathology Report Narrative • Procedure Note • Progress Note 	Patient Demographics <ul style="list-style-type: none"> • First Name • Last Name • Previous Name • Middle Name (including middle initial) • Suffix • Birth Sex • Date of Birth • Race • Ethnicity • Preferred Language • Address *NEW • Phone Number *NEW 	Unique Device Identifier(s) for a Patient's Implantable Device(s)
Goals <ul style="list-style-type: none"> • Patient Goals 	Problems 	Vital Signs <ul style="list-style-type: none"> • Diastolic Blood Pressure • Systolic Blood Pressure • Body Height • Body Weight • Heart Rate • Respiratory rate • Body Temperature • Pulse oximetry • Inhaled oxygen concentration • Pediatric Vital Signs *NEW <ul style="list-style-type: none"> - BMI percentile per age and sex for youth 2-20 - Weight for age per length and sex - Occipital-frontal circumference for children < 3 years old
Health Concerns 	Procedures 	
Immunizations 		

Trusted Exchange Framework and Common Agreement (TEFCA)

The Cures Act requires ONC to develop or support a trusted exchange framework, including a common agreement, among HINs nationwide with the goal of enabling data exchange across disparate HINs. TEFCA is intended to provide a single “on-ramp” to nationwide connectivity while advancing a landscape where EHI securely follows the patient and can be found and delivered when and where it is needed. TEFCA is comprised of two distinct components, the Trusted Exchange Framework (TEF) and the Common Agreement. The TEF describes a common set of principles that facilitate trust between HINs. The Common Agreement will provide the governance and technical requirements necessary to scale a functioning system of connected HINs that will grow over time to meet the demands of individuals, clinicians, and payers. Individuals will be given the opportunity to make a meaningful choice about how their data can be used, disclosed, or exchanged via the Common Agreement. After gathering initial stakeholder input, ONC released the first draft of TEFCA in January 2018 and the second draft in April 2019 for public comment.

Key changes from draft 1 to draft 2 include:

- Exchange purposes updated
- QHIN definition broadened
- QHIN message delivery added
- QHIN Technical Framework added
- Timelines extended

Recognized Coordinating Entity (RCE)

On September 3, 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the RCE. The RCE will be responsible for developing, updating, implementing, and maintaining the Common Agreement. The RCE will also collaborate with ONC to designate and monitor QHINs, modify and update accompanying QHIN technical requirements, engage with stakeholders through virtual public listening

sessions, adjudicate noncompliance with the Common Agreement, and propose sustainability strategies to support TEFCA beyond the cooperative agreement's period of performance.²

CMS' Interoperability Rule

CMS' [Interoperability and Patient Access Proposed Rule](#) (hereafter, referred to as the CMS Interoperability Rule) introduces new policies that will expand patients' access to health information and improve the seamless exchange of data in healthcare. CMS proposes to require certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) payers to:

- Make a variety of information accessible to beneficiaries via APIs that adhere to the requirements established in ONC's Cures Act NPRM.
- If requested by the beneficiary, forward his or her information to a new plan designated by the beneficiary for up to five years after the beneficiary has disenrolled from the initial plan.
- Publish available electronic provider directory information to facilitate care coordination and health information exchange.

Other Federal Activities

Several other federal activities that impact the HITAC's priority target areas occurred during FY19, including:

- **OCR HIPAA Request for Information (RFI)**
OCR sought stakeholder feedback to identify changes that could be made to the HIPAA Rules to remove provisions that impede the transition to value-based care or that limit or discourage care coordination without providing meaningful privacy or security protections. In addition, OCR sought feedback on ways it can encourage, incentivize, or require covered entities to disclose protected health information (PHI) to other covered entities.³
- **EHR Modernization**
DoD and VA are both in the process of modernizing their EHRs with the aim of creating a seamless medical record that follows service members as they transition from active duty to veteran status.⁴ DoD anticipates completing its system-wide rollout in 2023. VA anticipates its rollout will be completed in 2028.⁵
- **U.S. Food and Drug Administration (FDA)**
The FDA is actively considering several changes to its medical device regulatory framework to account for new technologies and capabilities. For example, the FDA released a proposed framework for regulating modifications made to medical devices by artificial intelligence and machine learning.⁶ The FDA runs an ongoing pilot program to inform the development of a more streamlined and agile regulatory approach of software-based medical devices developed by manufacturers who have demonstrated a robust culture of quality and organizational excellence, and who are committed to monitoring the real-world performance of their products.⁷
- **NIH All of Us Research Program**
The All of Us Research Program is a longitudinal, national research cohort of an intended one million or more U.S. volunteers from which clinical, environmental, genetic, and behavioral data will be collected to enable precision medicine.⁸ All of Us is focused on collecting data from multiple sources,

including EHRs and mobile health technology.⁹ Through July 2019, more than a quarter-million people have completed the consent process and more than 200,000 participants have completed the initial steps of the program.¹⁰

- **Clinician Burden Reduction**

ONC, in partnership with CMS, released a draft strategy to reduce the regulatory and administrative burden that clinicians experience relative to the use of health IT and EHRs, as required by the Cures Act.¹¹ The draft strategy includes recommendations to reduce clinicians' time and effort needed to document information in EHRs, meet regulatory reporting requirements, and improve the usability of EHRs. HHS has taken several steps to reduce clinician burden. For example, CMS overhauled the requirements of the Medicare and Medicaid Promoting Interoperability Programs (Promoting Interoperability programs) and the Merit-based Incentive Payment System (MIPS) to focus on interoperability, increased flexibility, and patient access.¹² Additionally, ONC and CMS have established a collaboration with NCVHS and the Council for Affordable Quality Healthcare (CAQH) to identify solutions to reduce clinician burden of prior authorizations through process automation.¹³ Moreover, HHS released proposed rules in October 2019 to modernize and clarify the regulations that interpret the Stark Law and the Federal Anti-Kickback Statute. These reforms aim to reduce provider compliance burden and to foster valued-base care programs.¹⁴

- **Price Transparency**

On June 24, 2019, President Trump signed an Executive Order making it the policy of the federal government to increase the availability of meaningful price and quality information for patients.¹⁵ In July 2019, CMS released a proposed rule that would require hospitals to make their standard charges and a subset of negotiated charges available online in a machine-readable format.¹⁶ This change builds on a previous CMS requirement that hospitals make public a machine-readable list of their standard charges via the Internet and update the information at least annually.¹⁷ In November 2019, CMS announced its intention to issue a price transparency rule that will address the hospital proposal from July and propose an approach to health plan price transparency.¹⁸ Furthermore, in the Cures Act NPRM, ONC included an RFI on the parameters and implications of including price information within the scope of EHI for purposes of information blocking. The RFI sought public comment on what price information should be made available, what technical standards exist to support the sharing of pricing data, and what technical challenges are anticipated that could impede the flow of price information. From an operational standpoint, price information may be useful at the point of care. Incorporating discussions of healthcare costs with patients can inform and facilitate shared decision-making processes to establish treatment plans.¹⁹

- **Quality Measurement and Improvement**

Healthcare quality is an important priority for many federal agencies, including HHS. In order to measure the performance of healthcare processes, CMS implements many quality reporting initiatives. Data on quality measures are currently collected or reported to CMS through claims data, assessment instruments, chart abstractions, EHRs, or registries.²⁰ Generally, providers experience many challenges to accurately report these measures due to the complexity of reporting and data capture. CMS is currently exploring adopting FHIR[®]-based quality measurement reporting.²¹

As mentioned above, additional discussions of federal activities are detailed within the priority target areas and topics below.

Priority Target Area: Interoperability

Background

During the past decade, hospitals and physician offices have made tremendous gains in shifting their recordkeeping from paper to computerized systems. The adoption rate of certified EHRs by non-federal acute care hospitals in 2017 was 96 percent.²² The adoption of certified EHRs by office-based physicians in 2017 was 79.7 percent.²³ Starting in 2019, all providers participating in the CMS Promoting Interoperability programs or MIPS must use the 2015 Edition CEHRT.²⁴ While most healthcare providers now use certified EHRs, interoperability remains fragmented and uneven. For example, as of 2017, only 41 percent of hospitals could find, send, receive, and integrate patient summary of care records from sources outside their health system.²⁵ Small, rural, and critical access hospitals trail other hospitals across all four domains of interoperability. As of 2017, only 10 percent of office-based physicians can find, send, receive, and integrate patient health information from outside sources.²⁶

Current State

Health Information Exchange

Connectivity and interoperability remain a challenge for providers because information that has been captured and is stored in health IT systems is still not easily shared and interoperable. Table 1 summarizes key measures of provider organizations' interoperability experiences.²⁷

Table 1- Percentage of office-based physicians and non-federal acute care hospitals that:	Office-based physicians (2017)	Non-federal acute care hospitals (2017)
Are electronically sending patient health information with any healthcare providers outside their organization	36%	88%
Are electronically receiving patient health information with any healthcare providers outside their organization	38%	74%
Can electronically find patient health information from sources outside their health system	53%	61%
Can integrate (e.g., without manual entry) health information received electronically into their health IT	28%	53%
Can find, send, receive, and integrate patient health information from outside sources	10%	41%
Had necessary patient health information electronically available from healthcare providers or sources outside their systems at the point of care	32%	51%

In 2017, about one-third of physicians and 51 percent of hospitals indicated that patient health information from outside sources was electronically available at the point of care.²⁸ Among physicians who electronically received patient health information from outside providers, three-quarters used the information “sometimes or often” for clinical decision-making.²⁹ Fifty-nine percent of non-federal acute care hospitals “sometimes or often” used patient health information received electronically from outside providers or sources.³⁰ The ability to incorporate and reconcile data from external sources remains a key challenge for many hospitals and other providers. For hospitals and office-based physicians, the top two reasons cited for not using patients' health information electronically received from outside providers are (1) “it is difficult to integrate in the EHR” and (2) “information was not always available when needed.”³¹

Interoperability challenges are even greater for care providers who are not eligible for the CMS Promoting Interoperability programs, such as behavioral health and long-term post-acute care settings.³² For example, only 18 percent of skilled nursing facilities (SNFs) and 36 percent of home health agencies (HHAs) report that they integrate patient health information from outside sources that has been received electronically. Moreover, only 61.3 percent of psychiatric facilities used any EHR system, with only 40.8 percent of those facilities using a system that is certified.³³ These care settings can benefit greatly from having comprehensive information on a patient's care in the acute care setting.³⁴

Today, there are more than 100 HIEs and multiple nationwide organizations that support the electronic exchange of health information.³⁵ Although these organizations have made significant progress in expanding interoperability, connectivity across them has been limited for several reasons, including variations in data use agreements that govern exchange, technical approaches, and the type of exchange supported. The lack of connectivity limits appropriate access to health information by individuals, providers, and payers, unless they join multiple networks. As a result, individuals are burdened by having to access their health information via multiple portals, and healthcare providers must create many costly, point-to-point interfaces to send and receive needed data. For example, 78 percent of hospitals used more than one electronic method to send records and more than 50 percent used four or more methods to do so.³⁶ Moving forward, connectivity between HIEs and nationwide organizations will be heavily influenced by the implementation of TEFCA. Historically, existing HINs often require data reciprocity tied to at least treatment purposes to exchange data.³⁷ However, TEFCA will expand the required reciprocity of data exchange to a much broader set of Exchange Purposes.³⁸

Unique Device Identifier

A UDI is an alphanumeric code that identifies a specific device that may be added to relevant records such as hospital purchase orders, patients' health records, or insurance claim forms. The UDI enables device tracking through the healthcare system and the ability to quickly identify faulty products and issue recalls, thereby improving patient safety.³⁹ In 2013, the FDA published a regulation, *Unique Device Identification System*, which requires UDIs for medical devices to help track products used in patient care. After full implementation is achieved by September 2020, most medical devices sold in the United States will include a UDI that is both human- and machine-readable.⁴⁰

HHS has taken steps to advance the capture of the UDI in EHRs, and additional measures remain under consideration. The 2015 Edition base EHR definition includes a requirement that providers have a certified health IT module that can record a UDI.⁴¹ In 2017, the X12 advisory committee, composed of hospital and health plan billing administrators, released a report that recommends partial adoption of UDI information on the next version of Medicare claims forms.⁴² CMS has not issued any formal decision regarding the adoption of UDI information on Medicare claims forms.

Sharing Data with the Research Community

Historically, clinical data and research data have been siloed (i.e., clinical data are not available to researchers and research data are not available in EHRs). However, there is an increased interest in utilizing EHR data in research trials. This integration faces numerous barriers, such as concerns over inconsistent standards used for EHR data collection and the lack of interoperability between research and healthcare systems. Advocates for this integration believe that it presents the opportunity to bring new therapies to patients sooner and potentially at a lower cost, and to accelerate learning health cycles.⁴³ Additionally, there is interest in integrating non-clinical data (such as PGHD or SDOH data) into research studies.

Non-traditional partnerships between technology corporations and academic researchers are beginning to be formed to advance health IT research. For example, NIH has partnered with Apple Inc. (Apple) to conduct a long-term study of women's health. Apple created a research app for participants' smartphones to record data for analyses.⁴⁴ Additionally, the genomics company 23andMe has signed partnerships with drug makers, universities, and nonprofit organizations to conduct research from its large consumer-based genomic database.⁴⁵

Health IT Support for Opioid Epidemic Response

Health IT is an important tool in addressing the opioid epidemic. The use of health IT has been demonstrated to improve adherence to opioid prescribing guidelines, increase the safety of prescribing for controlled substances, enhance clinician access to PDMPs, and expand access to substance use disorder treatment and recovery support.⁴⁶ In the past year, progress has been made to increase PDMP use and implement prescribing guidelines.

At the state level, PDMPs are electronic databases that track patient-level controlled substance prescriptions from pharmacy fill records. Currently, all states except Missouri have an operational statewide PDMP.⁴⁷ PDMPs can provide health authorities with timely information about prescribing and high-risk patient behaviors that may contribute to the opioid epidemic, which can facilitate a nimble and targeted response.⁴⁸ State policies vary on prescriber registration requirements, delegate access to check the PDMP, and prescriber and dispenser PDMP query requirements. ONC is collaborating with federal partners to support standard-based approaches to increase PDMP access and query functionality within EHRs.⁴⁹

Many state PDMPs need technical enhancements and significant EHR integrations to maximize PDMP utilization. A recent ONC analysis showed that one in three hospitals access their state's PDMP using their hospital's EHR. An ONC report found differences among state policies regarding EHR integration with a PDMP.⁵⁰ In addition, while there are two interstate hubs that enable the exchange of PDMP data between states, some states have expressed concerns that their PDMP vendor is restricting states' ability to connect with the hub of their preference.^{51,52,53}

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) was signed into law (Pub. L. No. 115-271) with specific sections that identify data use and health IT as tools to help address the opioid epidemic. Section 5042 of the SUPPORT Act requires that beginning October 1, 2021, states must have a Qualified PDMP and require Medicaid providers to query the PDMP before prescribing controlled substances to certain Medicaid beneficiaries.⁵⁴ The SUPPORT Act provides time-limited, 100 percent federal matching funds to upgrade PDMPs to support the integration of PDMP data in EHRs and facilitate the exchange of data between states.

In March 2016, the Centers for Disease Control and Prevention (CDC) published the *CDC Guideline for Prescribing Opioids for Chronic Pain* (CDC Guidelines). To improve the utilization of these CDC Guidelines, ONC and CDC have collaborated to help providers integrate clinical decision support (CDS) tools into their EHRs.⁵⁵ This integration utilizes FHIR® APIs and CDS Hooks to allow clinicians to receive targeted alerts based on the CDC Guidelines throughout their clinical workflow, incorporating patient-specific opioid history.⁵⁶ For example, a clinician would receive an alert asking if he/she would like to co-prescribe naloxone for patients who meet certain risk criteria as defined by the CDC Guidelines.

Electronic prescribing of controlled substances (EPCS) allows providers to integrate prescription drug information for controlled substances into EHRs, which can improve patient safety and reduce diversion and fraud.⁵⁷ The rate of electronic prescribing of non-controlled substances is nearly 90 percent. Comparatively, the rate of EPCS is much lower. In 2017, 32 percent of office-based physicians who prescribed controlled substances did so electronically.⁵⁸ In 2016, only 11 percent of Medicare prescribers used EPCS.⁵⁹ The SUPPORT Act mandated that by 2021, all controlled substance prescriptions covered by Medicare Part D must be electronically prescribed.⁶⁰

As part of the Cures Act NPRM, ONC included an RFI seeking comment on how existing health IT certification criteria support opioid use disorder prevention and treatment, and if there are any additional areas that ONC should consider for effective implementation of health IT to help address opioid use disorder prevention and treatment.⁶¹

Patient Matching and Verification

Patient matching is the process of comparing several demographic data elements from different health IT systems to determine if they refer to the same patient.⁶² The ability to complete patient matching efficiently, accurately, and at scale has long been identified as key to the success of the nation's health IT infrastructure. Accurate patient matching is essential to protecting patient privacy and ensuring patient safety.⁶³ Incorrect matching can lead to the inclusion of the wrong patient's health information in another patient's record. This can result in privacy and safety issues.

The Cures Act required the Government Accountability Office (GAO) to study patient matching. The resulting GAO report noted that accurate patient matching rates vary widely across healthcare organizations and are difficult to compare because organizations can calculate the rate differently.⁶⁴ Healthcare organizations generally agree that current match rates for data that are shared across organizations are inadequate and must be improved.⁶⁵ However, many stakeholders believe that no single effort, including a national patient identifier, will solve the patient matching challenge.⁶⁶

Most often, organizations use demographic data elements and a matching algorithm to determine if a record should be linked or not. ONC has adopted standards for some demographic data elements used for patient matching in the CCDS, while other elements have no widely adopted format.⁶⁷ ONC's Patient Matching, Aggregating and Linking (PMAL) project was established to (1) identify and test standards for matching patient data across and in between multiple types of data sets (e.g., research, clinical, and claims) to support research data infrastructure, and (2) identify and improve algorithms that can be used to reliably perform patient matching. The project included pilot projects and other activities, such as prize challenges, to address data quality, help improve patient match rates, and promote data standardization to advance interoperability. The PMAL project was launched in June 2015, and the final report was published in August 2019.⁶⁸

Healthcare organizations and health IT developers are beginning to leverage referential matching and machine learning to improve patient matching. Referential matching leverages demographic data from external third-party data sets to inform how patient linkages can be made. Instead of comparing demographic data from only two patient records – one from the sending system and the other from the receiving system – referential matching technologies use additional external data sources to develop a more complete profile of the patient, which can improve matching.⁶⁹ For patient matching, machine learning can be applied to help automate the improvement of patient matching algorithms and to automate the resolution of matches that traditionally would have been considered “too close to call” by

the algorithm (and therefore would have required manual human intervention to determine if the records should be linked or not).⁷⁰

Exchange of SDOH Data

SDOH are defined as “the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life.” This information can be used to identify patient-specific needs, enhance patient engagement, and share information across healthcare and social service organizations.^{71,72,73} SDOH data can come from a wide variety of sources, including patient-reported data or publicly available data such as voting or criminal records, credit history, or lifestyle information.

Despite strong evidence linking patients' social circumstances to their health status, the healthcare system faces challenges with using health IT to capture, share, and exchange SDOH data for healthcare delivery, improvement, and coordination.⁷⁴ Therefore, the private and public sectors are collaborating on best practices for data collection, information sharing, and research and evaluation addressing social risk factors. ONC is working to advance health IT in support of the care continuum with stakeholders such as HL7® on the Gravity Project that are developing consensus-based documentation standards to capture SDOH data as part of the patient health record and on developing a FHIR® implementation guide.⁷⁵ The Gravity Project is part of the Social Interventions Research and Evaluation Network (SIREN) that advances efforts to identify and address social risks in healthcare settings by disseminating research resources and evaluating SDOH interventions.⁷⁶ Through the Health IT Certification Program, ONC supports the interoperable capture, use, and exchange of SDOH data. Seventy-two health IT developers, representing the technology used by approximately half of all office-based clinicians and nearly a third of hospitals, have certified 93 unique products to the voluntary SDOH-related certification criterion.⁷⁷

CMS is testing new payment models, such as the Accountable Health Communities (AHC) Model, to reduce expenditures and improve health outcomes. The AHC Model supports clinicians' use of health-related social needs screening tools to identify needs related to SDOH.⁷⁸ CMS is supporting state Medicaid agencies' efforts to address social needs through 1115 demonstration reform waivers, which are providing financing for innovative models to improve system capacity and establish payment incentives to address SDOH.⁷⁹

Additionally, some regions are improving the exchange of SDOH data through the creation of CIEs.⁸⁰ CIEs enable network partners to use common technology and resources for shared community care planning and referrals across health and social services.⁸¹

Association between EHRs and Patient Safety

A well-designed, properly implemented, and responsibly used EHR can improve patient safety by better supporting clinical workflows and decision making.⁸² However, EHRs can also pose new patient safety risks. EHRs can be programmed to send out alerts to providers. These alerts can range from clinical decision support to medication allergy alerts. On average, a physician will receive more than 100 pop-up alerts per day.⁸³ If providers receive too many alerts, they may begin to experience “alert overload” and have difficulty parsing out those that include meaningful information.⁸⁴ Additionally, the way EHRs are configured for a specific provider can lead to patient safety risks. For example, the EHR may allow similar information to be captured in multiple places, leading to the possibility that clinicians may miss or misread information. Moreover, value conventions for data fields, such as weight (pound vs. kilogram), may not be apparent to providers, which could lead to medication prescription errors.⁸⁵ Errors within EHRs occur regularly, with estimates that 1 in 10 individuals have requested a correction in their medical record.^{86,87}

These data integrity challenges can affect decisions about clinical care and health policy, and present downstream consequences for patient safety, research, and public health purposes.⁸⁸

ONC has developed several resources, including the [Safety Assurance Factors of EHR Resilience \(SAFER\) Guides](#), to strengthen patient safety efforts and reduce medical errors associated with health IT.⁸⁹ Usability concerns have led to strong calls for additional measures to ensure patient safety. For instance, a nationwide awareness campaign named “Everybody Has Responsibilities” has been formed to call stakeholders to take action on this issue.⁹⁰ The campaign includes videos that describe the clinician user experiences and workflows within EHRs that can pose safety risks.⁹¹ Additionally, some providers and other stakeholders have called for specific attention to be placed on the unique patient safety concerns that arise in the pediatric setting.⁹² Pediatric patients are especially vulnerable to medication errors caused by EHR use due to their different physical characteristics, lack of testing of many medications in children, and dependence on parents and care providers to prevent medical errors.⁹³

HL7® FHIR® Standard

The HL7® FHIR® standard is a representational state transfer (REST)-based standard designed to enable the exchange of information related to healthcare.⁹⁴ This information includes clinical data as well as healthcare-related administrative, public health, and research data. The FHIR standard builds on previous data format standards from HL7. It facilitates interoperability between legacy health IT systems, eases the provision of healthcare information to healthcare providers and individuals on a variety of devices such as computers, tablets, and cell phones, and allows third-party app developers to provide medical apps that can be easily integrated into existing systems. FHIR provides an alternative to document-centric approaches like the Consolidated-Clinical Document Architecture (C-CDA) by directly exposing discrete data elements as services. For example, basic elements of healthcare data such as patient identifying information, admissions, diagnostic reports, and medications can be retrieved and manipulated via their own resource uniform resource locator (URL).

In the Cures Act NPRM, ONC proposes to adopt FHIR® as the required API standard for certified products, replacing the existing functionality-based certification requirements which must be used by providers participating in the CMS Promoting Interoperability programs and MIPS starting in 2019. ONC determined that more than 51 percent of developers certified to § 170.315(g)(8), one of the existing functionality-based API criteria, are using a version of FHIR and that those developers cover approximately 87 percent of hospitals and 69 percent of clinicians.⁹⁵ ONC sought stakeholder feedback on the appropriate version of FHIR to adopt in the final Cures rule. In addition, CMS proposes in the CMS Interoperability Rule to require certain payers to use FHIR® to expose data to their beneficiaries.⁹⁶ NIH and the Agency for Healthcare Research and Quality (AHRQ) have begun promoting the use of FHIR in their funded clinical research projects.^{97, 98}

In addition, several industry groups are actively working to use, improve, and refine the FHIR® standard. The HL7 Argonaut Project is a private-sector initiative working to rapidly develop and implement the first-generation HL7® FHIR®-based API to support the 2015 Edition API requirements. The Argonaut Project brings together a variety of health IT developers and provider organizations.⁹⁹ HL7 published FHIR Release 4, the first normative version of FHIR.¹⁰⁰ HL7 is also leading the Da Vinci Project to accelerate the adoption of FHIR as a standard to support and integrate value-based care data exchange across communities.¹⁰¹ National interoperability initiatives such as DirectTrust, The Sequoia Project, and CommonWell Health Alliance are working to advance the use of FHIR in their efforts.^{102, 103, 104} To help synthesize these initiatives, ONC has convened the FHIR at Scale Taskforce (FAST). This task force, composed of healthcare

industry stakeholders and health IT experts, is tasked with identifying scalability gaps and proposing solutions that can be implemented on a large scale.¹⁰⁵

Use of Administrative Data

Enabling the interoperable electronic exchange of administrative and clinical information can help reduce the burden of certain administrative tasks such as billing, prior authorization, and benefits determinations. For example, the use of health IT has increased the speed and consistency of the Social Security Administration's (SSA) disability determination process. The SSA processes more than three million disability claims annually and requests 15 million medical records from approximately 500,000 providers when making decisions. The use of health IT has cut the time it takes the SSA to receive records from weeks or months to minutes or hours.¹⁰⁶

Access to administrative data, such as claims data or price information, can improve providers' understanding of the care their patients have received across the healthcare system. Providers participating in alternative payment models are particularly interested in determining how to leverage and combine clinical and administrative data to inform their care management programs and clinical decision making.¹⁰⁷ Providers still face challenges aggregating and normalizing clinical and administrative data in a manner that makes data actionable. HL7[®] and CAQH are working together to improve the automation and interoperability of administrative and clinical data.¹⁰⁸ In addition, the Da Vinci Project has a use case supporting payers sending administrative data to providers using FHIR[®].¹⁰⁹

Priority Target Area: Privacy and Security

Background

As interoperability and access to patient health information expand, the privacy and security of health data are primary concerns for stakeholders. Robust privacy and security practices are important considerations in advancing and maintaining trust in interoperability, while poor privacy and security practices heighten the vulnerability of patient information stored in health information systems and on devices. In addition, inadequate privacy and security practices have the potential to create data management problems for healthcare providers via unauthorized and/or unintended disclosure, ransomware, and other avenues.

Privacy and security regulations are sometimes cited as a barrier to sharing health information, although many of these concerns have been ameliorated over time, sometimes simply through education about what the law requires. Furthermore, lowering the cost of information exchange or increasing financial incentives may boost provider participation more than further reducing legal barriers.¹¹⁰

Current State

Protections for Data Generated Outside of the HIPAA Framework

HIPAA Privacy and Security Rules protect data when they are created by, or in the custody of, a covered entity or a business associate. If data are created by an entity that is not a covered entity or business associate, HIPAA does not apply.¹¹¹ If data covered by HIPAA are disclosed to an entity not subject to HIPAA, then the data in that entity's possession are no longer subject to HIPAA.¹¹² In recent years, more health data have begun to be collected, shared, and used by entities that fall outside the traditional healthcare community covered by HIPAA, such as SDOH data from external sources, digital apps, and

devices that collect PGHD. This fact is often not transparent to patients.¹¹³ Although digital health apps typically present their privacy policies and proposed uses for the data in a Terms-of-Use format, studies have shown that more than 90 percent of health app users accept these terms of use without actually reading the details.¹¹⁴ The Federal Trade Commission (FTC) has enforcement authority over the privacy practices of many entities that fall outside of HIPAA. However, the FTC's enforcement authority applies to acts and practices that are unfair and deceptive and does not prescribe privacy requirements that must be adopted or followed.¹¹⁵

In response to the current landscape of health data privacy protections, NCVHS submitted its *13th Report to Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996* in February 2019 with a number of recommended actions for Congress and the Executive Branch. NCVHS recommended that Congress establish federal privacy and security protections for patient data held by organizations that are not covered entities or business associates. It also recommended that HHS issue guidance on reasonable steps covered entities and business associates should take to protect patient data (including de-identified data) when disclosing it to entities that are not covered by HIPAA or other privacy laws.¹¹⁶

Federal Privacy Laws and Regulations beyond HIPAA

Several federal privacy laws and regulations provide additional protections beyond HIPAA. These include 42 CFR Part 2 and FERPA (20 U.S.C. § 1232g; 34 CFR Part 99), as well as the Cures Act NPRM.

42 CFR Part 2 protects the confidentiality of patient records related to substance use disorders by restricting the circumstances under which federally assisted 42 CFR Part 2 programs can disclose information. Unless an individual provides specific written consent, 42 CFR Part 2 programs are prohibited from disclosing any information that would identify a person as having or having had a substance use disorder. The Substance Abuse and Mental Health Services Administration (SAMHSA) and ONC released fact sheets to assist with the application of the Part 2 provisions across different environments, including through HIE mechanisms and in provider office settings.¹¹⁷ In August 2019, SAMHSA published a notice of proposed rulemaking to make revisions to 42 CFR Part 2 to improve coordination of care for patients with substance use disorders while still preserving the original foundation of confidentiality.¹¹⁸

FERPA is a federal law that protects the privacy of student education records. This includes students' health records maintained by a school nurse or covered institution and generally requires the consent of the parent or the student to share data.¹¹⁹ The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. The HIPAA Privacy Rule specifically excludes from PHI student education records that are protected by FERPA.¹²⁰ As a result, health IT used to support providers in institutions covered by FERPA must address the unique privacy requirements of FERPA, which differ from HIPAA. For example, under HIPAA providers can electronically submit immunization information to public health agencies without patient authorization, while explicit consent is required to electronically submit such data covered by FERPA.¹²¹

In the Cures Act NPRM, ONC proposes a variety of new certification criteria that are intended to improve the ability of providers and patients to control the disclosure of their data. The new criteria support the ability of patients to share their data with a third-party app of their choice. Providers will have the ability to export all the data in their EHR, to document patient consent decisions, and to share only segments of a patient's record.¹²²

International Data Exchange and Privacy Considerations

The European Union's (EU) GDPR sets new rules on how companies manage and share personal data. The GDPR is more expansive than HIPAA as it uses a broader definition of personal data and covers any information associated with an "identified or identifiable natural person," including computer IP addresses, photographs, and credit card data.¹²³ U.S. companies, including health IT developers, must comply with the GDPR if the organization is doing business in the EU, processes personal data of EU individuals and data for goods and services offered in the EU, and monitors the behavior of EU individuals.¹²⁴ The adoption of the GDPR has catalyzed conversations in the United States and around the world on expanding consumer privacy protections and providing consumers the right to have their personal data erased.¹²⁵

At the first anniversary of the GDPR's implementation in May 2019, more than 280,000 cases including complaints and data breach notifications across 27 countries have been brought, with 63 percent closed and 37 percent ongoing.¹²⁶ From the closed cases, nearly \$62 million in fines were collected.¹²⁷ However, none of the anticipated billion-dollar fines have been collected.¹²⁸ Enforcement actions have covered a variety of violations ranging from traditional privacy issues to performing excessive surveillance and scraping data from public sources with inadequate notice.¹²⁹ There is much still to be determined about how the GDPR will be implemented and enforced.¹³⁰

State Data Exchange and Privacy Considerations

Many states have laws and regulations to protect the privacy of health information, which often have stricter privacy protections and requirements on use and disclosure than the HIPAA Privacy Rule. These statutes and regulations vary from state to state, often narrowly targeting a population, health condition, information collection effort, or specific types of healthcare organizations.¹³¹ The variation can cause confusion among exchange partners and make it difficult and expensive to manage technology to ensure privacy compliance.¹³² Hospital systems and provider groups set their own privacy policies, which may vary based on their interpretation of state privacy laws and regulations. These privacy policies can be based on a restrictive interpretation of privacy laws due to confusion about the law's intent, therefore adding unnecessary burdens to information exchange.¹³³ The spectrum of state privacy laws has been catalogued by several organizations.^{134,135,136}

Some states are adjusting mandated consent policies to opt-out from opt-in to enable broader, secure exchange of health information. Patient consent policies typically fall under two broad categories: (1) opt-out, i.e., patients are automatically enrolled in an HIE but are given the opportunity to opt out of having their information stored and/or disclosed by the HIE; and (2) opt-in, i.e., patient consent is required for patient health information to be stored and/or disclosed by the HIE.¹³⁷ As of 2016, among 31 states with laws addressing privacy and exchange, 16 followed the opt-out approach, eight described an opt-in process, and the rest adopted other approaches to participation in an HIE. Twenty-three states imposed specific confidentiality requirements on HIE users and five mentioned confidentiality without providing specific requirements.¹³⁸

A number of states are exploring, and a few have adopted, expanded general consumer privacy protections that are broader or stricter than HIPAA to increase consumers' control over how their data are used.^{139,140} The proliferation of such state laws may raise questions about the role of the federal government in coordinating a patchwork of privacy and security protection nationwide, especially when data are shared across state lines. For example, effective January 1, 2020, the California Consumer Privacy Act of 2018 (CCPA) will expand the privacy rights of California consumers as well as require businesses to

disclose what, why, and how consumers' personal information is being used.¹⁴¹ Failure to comply with this new law could expose businesses to costly civil penalties. The law applies to businesses that collect, use, or share personal information of California residents. The California Legislature is currently considering a number of amendments to CCPA to address stakeholder feedback.¹⁴²

De-identification and Artificial Intelligence

Large-scale health data sets can provide valuable insights for researchers, policymakers, analytics developers, technology companies, and patients (e.g., through patient-powered research networks). Under HIPAA privacy regulations, a covered entity is not restricted from disclosing PHI if it is de-identified. Under these regulations, health data are considered de-identified if they have undergone either (1) Expert Determination, a formal determination by a qualified expert; or (2) the Safe Harbor Method, the removal of specified individual identifiers as well as the absence of actual knowledge by the covered entity that the remaining information could be used to identify the individual.¹⁴³ The Safe Harbor Method is the most commonly used method for de-identification. However, the ubiquity of publicly available online information, coupled with these de-identified health data sets, has introduced the possibility that de-identified data can be "re-identified."

For example, researchers have demonstrated that statewide inpatient discharge data can be compared to publicly available data sources, such as news stories or voter databases, and result in a high rate of re-identification. Even when demonstrating HIPAA Safe Harbor standards for de-identification, health data still may be re-identified, albeit at lower rates.¹⁴⁴ These demonstrations of re-identifications have been augmented with the introduction of artificial intelligence technologies. For instance, a recent study showed that the use of an artificial intelligence algorithm allowed the identification of individuals through the pairing of physical activity sensor data with publicly available demographic data.¹⁴⁵ Artificial intelligence allows re-identification to occur at a larger scale and faster pace, whereas early studies required tremendous labor to re-identify individuals. These examples of re-identification capabilities have resulted in calls for more stringent privacy protections than provided by current HIPAA rules.¹⁴⁶

Cybersecurity

With an increasing prevalence of cybersecurity threats, providers must be at the forefront of security practices to protect their IT infrastructure.¹⁴⁷ In 2019, the incidences of cybersecurity breaches within the healthcare sector have dramatically increased. These breaches can lead to enforcement penalties and create patient safety risks and a loss of trust for affected systems.¹⁴⁸ In addition to the IT infrastructure, providers are increasingly using mobile devices and connected devices, such as medical equipment or IoT devices, to care for their patients.¹⁴⁹ These devices are used to store, process, and transmit patient information and can expose a system to a cybersecurity risk if not secured properly.

There are several cybersecurity frameworks, both subscription-based and publicly available, recommended for improving the security of IT networks. Subscription-based frameworks include the Health Information Trust Alliance (HITRUST) Common Security Framework (CSF). Publicly available frameworks include the International Organization for Standardization (ISO) standards, Center for Internet Security (CIS) Critical Security Controls for Effective Cyber Defense, and National Institute of Standards and Technology (NIST) Cybersecurity Framework.¹⁵⁰ These frameworks consist of standards, guidelines, and best practices to manage cybersecurity-related risk.¹⁵¹

Priority Target Area: Patient Access to Information

Background

Patients' electronic access and use of their health information are critical to enabling individuals to better monitor their health as well as manage and coordinate their care.¹⁵² In 2019, HHS has made a major push to accelerate and improve patients' access to and control over their health information. Proposals in the Cures Act NPRM and CMS Interoperability Rule will increase choice and competition while fostering innovation that promotes patient access to and control over their health information.¹⁵³ For example, the Cures Act NPRM proposes to require that patients have the ability to access their data at no cost.

Current State

Patient-Controlled Data Collection, Access, and Sharing

Availability for patients to access their health information electronically from providers and payers is increasing. According to the 2018 Health Information National Trends Survey (HINTS), 51 percent of patients have been offered online access to medical records by a healthcare provider or health insurer and online access to medical records. This rate did not change from 2017. Three in 10 individuals were offered access to their online medical record and viewed it at least once within the year. Of those who were offered access, 58 percent accessed their records online. More than half of those accessing their records used them to communicate with a healthcare provider.¹⁵⁴ While access to these technologies, such as patient portals and applications, is important, the usability of these tools must also be considered. Despite having increased access to their health data, patients do not always understand this information or its implications.¹⁵⁵ For example, test result display and navigation difficulties were found to be the biggest challenges for patient portal users.¹⁵⁶ In addition to health literacy challenges, patients face accessibility obstacles of small print size and other visual barriers, and limited support for non-English languages.¹⁵⁷

The use of APIs can improve individuals' electronic access to their health information and better support the growing market of patient-facing apps that are intended to allow individuals to access, aggregate, and act on their health information. HHS has multiple activities focused on increasing patient access to their data through APIs. The CMS Blue Button 2.0 initiative created an API through which Medicare beneficiaries can access their data at no cost and direct data to a participating app of their choice.¹⁵⁸ The CMS Promoting Interoperability programs and MIPS require providers to give patients access to their data via an API. The Cures Act NPRM proposes to require that these APIs are FHIR®-compliant and provide patients access to their data at no cost. In its Interoperability Rule, CMS proposes to require several types of payers to implement, test, and monitor FHIR-based APIs to make patient claims and other health information available to patients through third-party apps and developers.¹⁵⁹

In addition, the private sector is providing innovative opportunities for patients to access, manage, and share their health data with trusted parties. Apple worked with health systems and health IT developers to allow patients to access and aggregate patient health information from multiple institutions. The Apple Health Records EHR data viewer uses the FHIR® standard to collect patient health data from disparate sources and populate user devices with clinical information in a unified, consumer-friendly interface.¹⁶⁰ In 2019, Apple enabled the ability of any healthcare provider with a compatible EHR to self-register in the program.¹⁶¹ An analogous program, named CommonHealth, is being developed by a coalition of organizations to create an open-source platform to enable Android phone users to access and share their

health records.¹⁶² The CARIN Alliance is facilitating increased consumer-mediated exchange through mobile apps and has established a code of conduct for third-party mobile apps to address privacy concerns about healthcare data access, exchange, and use.¹⁶³

An early evaluation of patient engagement that allowed patients to download clinical data onto smartphone apps via FHIR®-based APIs showed minimal but growing usage of this technology among patients of 12 early adopter health systems that all use the same EHR vendor.¹⁶⁴

Policy and Trust Issues for APIs

Starting in 2019, the CMS Promoting Interoperability programs and MIPS require participating providers to give patients access to their data through an API, in addition to the previous patient access requirements. It is hoped that these new API requirements will make data more accessible to patients and the third-party apps of their choosing. Healthcare providers and health IT developers have expressed many policy- and trust-related concerns about sharing data with patients via APIs and believe that additional federal guidance is necessary to support implementation.¹⁶⁵ They are concerned that consumers will unknowingly lose their HIPAA data protection by sharing their data with third-party apps and that app developers will aggregate, share, and monetize patient data in ways that are not transparent to patients.^{166,167,168} In April 2019, OCR released five frequently asked questions (FAQs) seeking to provide guidance on some of the policy, trust, and liability issues related to APIs that stakeholders have raised.¹⁶⁹

Use and Sharing of PGHD

Patients are beginning to use devices and apps to manage their health information and care. The GAO found that as of 2017, one-third of individuals used an electronic device to monitor their health and one-third of smartphone or tablet owners used their devices to discuss health decisions with their healthcare team. Nearly one in five smartphone, tablet, or electronic monitoring device owners shared health information collected by their devices with a health professional.¹⁷⁰ Patient-reported outcomes (PROs), a type of PGHD, are commonly collected within clinical trials but less so in clinical care. However, some providers, such as oncologists, are starting to use PROs in non-research settings to improve clinical care.¹⁷¹

PGHD captured and shared in a non-clinical setting can offer point-of-care insights into a patient's health status and inform progress against a treatment plan, potentially enabling care teams to make more timely, better-informed decisions with patients. Consumer interest in the use of PGHD has increased with the growing prevalence of wearable fitness trackers and mobile health apps. Providers and researchers increasingly are looking for ways to capitalize on the pervasiveness of these devices and the abundance of data being generated by patients.¹⁷² A recent study examining early experiences with PGHD found that the primary barrier to use by patients and providers is uncertainty about the value of PGHD.¹⁷³

There are multiple opportunities for PGHD use to help advance value-based payment models, clinical care, telehealth, and research efforts. For example, CMS unbundled payment for Current Procedural Terminology (CPT®) code 99091 for remote patient monitoring in the 2018 Medicare physician fee schedule to better support telehealth services.¹⁷⁴ In the 2020 physician fee schedule proposed rule, CMS requested comment on how it could integrate a PGHD requirement into MIPS in the future.¹⁷⁵ Digital technologies are facilitating patient-centered research through crowdsourcing. For example, the All of Us Research Program is attempting to achieve a critical mass of data by building a research program of more than 1 million people's donated health data.¹⁷⁶

Emerging Issues across the Priority Target Areas

In developing the Landscape Analysis, the Annual Report Workgroup identified multiple emerging issues that will be of growing importance to the deliberations of the HITAC moving forward. Each emerging issue is addressed briefly below to introduce it and is being closely tracked by the Annual Report Workgroup for consideration in future reports.

- **Integration of Health Data from the IoT**

The IoT refers to the technology and connectivity of various objects including appliances, devices, wearables, and sensors to the Internet or other networks.¹⁷⁷ Connecting these objects together enables organizations to collect and analyze data to gather new insights into how to optimize processes, improve decisions, and automate responses to events. The IoT has many potential applications in healthcare, such as remote monitoring, medical device integration, smart pills, and smart facilities (i.e., inventory management).¹⁷⁸ PGHD can be collected and shared using the IoT.

However, there is limited interoperability across IoT developers.¹⁷⁹ As IoT objects become more integrated with health IT systems, security risks increase. The FTC has raised strong privacy and security concerns related to the IoT. These include the potential for unauthorized access, misuse of personal information, and the ability of IoT objects to be used to facilitate attacks on other systems.¹⁸⁰ Additional concerns have been raised regarding the challenges of informed consent for users of IoT technologies.¹⁸¹ The FDA has issued formal guidance on how medical device manufacturers should handle reports about cyber vulnerabilities.¹⁸²

- **Prescription of Apps, i.e., Digiceuticals**

Digital therapeutics or “digiceuticals” is the use of digital apps in a formal role in managing a condition or symptom. The digital app could be prescribed by a clinician as a standalone treatment or in conjunction with other treatments.¹⁸³ Digiceuticals typically have one or more of the following capabilities: (1) measure and record data; (2) analyze and make recommendations from the data; and (3) communicate and educate about the findings. Some digital apps are intended to be used in clinical tests and therefore will require regulatory approval from the FDA.¹⁸⁴ One large prescription benefit manager has introduced its own digital health formulary that includes a curated set of digital apps. This tool can increase consumers’ access to technology that can help improve their health. It can also be leveraged by payers to reduce administrative burden and improve affordability, and by digital app developers as a path to a broader market.¹⁸⁵

- **Linking Genetic Data to Social Behavior, i.e., Sociogenomics**

Sociogenomics is an emerging field that attempts to find the genetic basis and evolution of social behavior. Researchers are examining the role of social factors on the expression of individual genes.¹⁸⁶ Advocates of sociogenomics envision making information available that predicts the risk of contracting various diseases. Critics warn that sociogenomics could contribute to discrimination and without regulations could be used in reviewing job applicants and for calculating insurance premiums.¹⁸⁷

- **Machine Learning and Artificial Intelligence in Healthcare**

Machine learning, a subset of artificial intelligence, is the process by which a computer is able to improve its own performance by continuously incorporating new data into an existing statistical model.¹⁸⁸ Machine learning has many potential applications in healthcare to help generate insights from data including improving the discovery of new drugs, the use of existing drugs, patient matching,

and assisting with diagnostics and treatment recommendations.¹⁸⁹ Concerns have been raised that insights generated by machine learning may perpetuate existing biases that are built into the data set with which the system is trained (e.g., bias due to a non-representative patient population, geographical spread, genetic background).¹⁹⁰ These concerns stem from the opacity of a machine learning algorithm's decision-making logic. In response, the EU has proposed in the GDPR a "right to explanation" to all EU citizens who are subject to "automated decision-making."¹⁹¹ These regulations would force machine learning programmers to expose the decision-making process to users; however, due to the millions of parameters within some recognition-based algorithms, critics are concerned that this disclosure will not be possible.¹⁹²

- **Sharing Diagnostic Imaging: The Challenge of Large Media Files**

Certain large media files, such as audio and video recordings and photographs, lack agreed upon and widely adopted interoperability standards. Medical images are one example of a large media file that does have agreed upon interoperability standards but the estimated adoption level is unknown.¹⁹³ Even where standards exist, providers still often face difficulty in accessing these files from sources outside their health system.¹⁹⁴ Patients also face difficulty in having their images shared electronically; for example, as a workaround, patients often must bring a compact disc (CD) with copies of the images to their provider.¹⁹⁵

- **Next-Generation Wireless Technology Implementation**

5G, the informal name for the next (the fifth) generation of wide-area wireless technology, is anticipated to move data up to 100 times faster than existing wireless networks can.¹⁹⁶ This technology is more responsive and offers the ability to simultaneously connect more devices than current wireless technology. The four largest U.S.-based telephone carriers have deployed 5G with limited availability. Widespread availability is not anticipated until 2021 or later.¹⁹⁷ The increased speed of 5G-enabled networks will support a variety of healthcare uses such as improving the reliability of telehealth services, supporting the IoT, and supporting augmented and virtual reality use cases (e.g., training simulations and patient pain management).¹⁹⁸

Health IT Infrastructure Gap Analysis

Priority Target Area: Interoperability

Challenges with Incorporation and Reconciliation of Data Received from Outside Sources

Clinicians face significant challenges in using data they receive from external sources (e.g., hospitals, other physician practices, payers, HIEs, SNFs, and patients). It is often difficult to ingest, reconcile, and integrate the data (e.g., care summary documents, laboratory results, PGHD) received from these disparate data sources into clinical and operational workflows. As data exchange increases across the country, these challenges will continue to grow in scope and scale. Providers place importance in the evaluation of the quality and provenance of incorporated data, as well as the use of PGHD. Challenges also persist with matching outside data to the correct patient's record, receiving data in a structured format, and enabling providers to view the incorporated data in a single view.

These challenges are also present from the patient's perspective. Patients who see unaffiliated providers will need to access multiple patient record systems to access their health data. For patients with complex medical histories, reconciliation across these systems is an obstacle. The need to access more than one patient record system also poses patient safety risks and creates barriers for patients attempting to develop a comprehensive health history.¹⁹⁹

Lack of Price Transparency

The healthcare system faces a persistent challenge of price transparency. CMS' initial efforts to advance price transparency by requiring hospitals to post their standard charges is an important first step. However, consumer advocates and hospitals believe that the requirements will not help patients understand their out-of-pocket cost for a specific procedure or help them compare costs. The long lists of thousands of goods and services posted on individual hospitals' websites have made it difficult for patients to find and use the information.

Even when patients have price comparison tools available to them, they rarely use the tools. Patients also need information about the quality of care to inform their decisions about which provider to select for a service. Today, some patients associate high prices for healthcare with high quality even though the evidence shows that quality and price are not correlated.²⁰⁰ The HITAC has noted a number of issues that should be considered by HHS in future rulemaking to address price transparency.²⁰¹

Limited Unique Device Identifier Integration

At present, UDI data are not frequently integrated into EHRs or administrative claims data.²⁰² As a result, medical device usage in patients is difficult to track. This limits the ability to identify device-related safety issues at patient and population levels and to implement appropriate device recalls.²⁰³ While certified health IT is required to capture UDIs for certain devices, the actual use by providers is unclear. Barriers to the integration of UDI into EHRs and claims data persist. Many providers have not made the necessary workflow changes to document UDI data in their EHRs, often leaving the field empty.²⁰⁴ Moreover, Medicare claims forms do not have a field to capture UDI data, although its addition has been proposed.²⁰⁵

Need for Clarification on the Use of Health Data Made Available Electronically for Research Purposes

While calls to integrate research and health data made available electronically are increasing, the feasibility of interoperability between these two data sources is uncertain. There is currently no common data standard to easily integrate, aggregate or compare data among research studies.²⁰⁶ NIH offers repositories of common data elements and common data models, but they are not harmonized with each other.²⁰⁷ Research studies must collect data in a specific, controlled manner; therefore concerns regarding EHR data quality exist. These concerns were validated in a recent study that showed that only 15 percent of U.S.-based clinical trials published in high-impact journals in 2017 could be feasibly replicated through analysis of administrative claims or EHR data. This suggests that clinical data can be a complement to research data, rather than a replacement.²⁰⁸ Researchers have also demonstrated an interest in integrating data generated outside of the clinical ecosystem (such as PGHD or SDOH data) into research studies. Additionally, there is a gap in guidelines for consent to the use and sharing of, data ownership of, and access to clinical data for research purposes.²⁰⁹ While patients may provide consent for clinical uses of their data, that consent does not necessarily carry over for that data to be used for research purposes. Innovations in the use of electronic consent models for research studies have shown success in helping patients better understand how their data from a research study may be shared.²¹⁰

Limited EHR Integration with PDMPs

Historically, there has been a lack of insight into efficient EHR integration with PDMPs. Point-to-point connections between a PDMP and multiple EHRs are expensive and challenge state resources. As of July 2019, nine states did not offer EHR integration with their PDMP.²¹¹ While limited concrete data exists on the level of EHR integration compared to web portal access to PDMP data, it appears that most providers still access PDMPs through an external web portal, even in states that support EHR integration. In addition, some PDMP functionality is only available through the web portal.²¹² Accessing the PDMP through an external web portal may disrupt a provider's clinical workflow within an EHR.²¹³

State laws or policies may prohibit PDMP data integration and storage within an EHR or HIE. As a result, providers must reference multiple systems to obtain a comprehensive picture of a patient's medical history, thereby increasing their workflow burden. State laws also vary significantly regarding access rights to the PDMP, which can create challenges in integrating data into EHRs. Some states have enacted delegate access policies to allow technicians or trainees the ability to access the PDMP, thereby adding additional resources to improve workflow burden.²¹⁴ However, a number of states only allow prescribers and dispensers access to the PDMP. Ultimately, these access and integration restrictions result in decreased utilization of the PDMP.²¹⁵

Need for Improved Patient Matching When Sharing Data

Patient matching errors can originate from multiple aspects of the patient care experience, such as patient registration or data sharing among organizations. Matching errors can result in inaccurate record creation, inadvertently merged records, and duplication of records. These errors can negatively impact healthcare costs and patient safety.²¹⁶ Many providers, payers, and health IT developers believe that the lack of a unique patient identifier and the lack of standardization of underlying demographic data elements used for patient matching limit their ability to effectively match patients.²¹⁷ Some stakeholders believe a national patient matching strategy is needed.²¹⁸ Due to the expected significant increase in the volume of data exchange in the coming years, and the implementation of relevant federal policies (i.e., implementation of the information blocking rule, APIs, and TEFCA), the need to improve patient matching will only increase.²¹⁹

Nascent Capture and Use of Social Determinants of Health Data

While the collection and use of SDOH data have garnered attention in the healthcare sector, there are challenges to operationalizing this data. Business models across healthcare sectors do not yet support the capture and use of SDOH data due to a lack of standards and data availability, patient matching challenges, and varying levels of technical maturity of community service providers' IT systems.²²⁰ If SDOH data are collected, it is usually documented in free text portions of the EHR, limiting the ability for data exchange across providers.²²¹ Due to these barriers, SDOH data are considered one of the most difficult types of information to share through HIEs. Furthermore, if these data are successfully collected, healthcare providers' lack of awareness of social resources can impede connecting individuals with needed follow-up services. In addition, the inability to effectively share SDOH data impedes cross-sector sharing of human services, housing, education, and transportation data important to population health activities.

EHR-related Adverse Patient Safety Events

Concerns that EHRs can adversely affect patient safety have been raised after patient safety incidents occur. Yet, there is currently little data available on safety events originating from EHRs because some EHR contracts prohibit providers from sharing this information publicly. There is currently no centralized, transparent repository of this information, making it difficult to identify patterns and trends.²²² However, the Cures Act and Cures Act NPRM have provisions that will increase patient safety testing of certification products and prohibit limitations on communications related to usability. In addition, the Cures Act mandates the establishment of an EHR Reporting Program, which will capture information from providers and health IT developers on usability and patient safety. The HITAC provided recommendations on how to strengthen aspects of the Cures Act NPRM proposals.²²³

Unmet Needs of Additional Care Settings and Stakeholder Groups

For the healthcare industry to successfully migrate from a fee-for-service (FFS) model to alternative payment models (APMs), EHI must flow to the correct location when needed across the entire care continuum.²²⁴ Today, many healthcare providers that were not eligible to receive incentive payments under the CMS Promoting Interoperability programs have lower rates of adoption of EHRs and use of HIE when compared to eligible hospitals and clinicians.²²⁵ The disparity of HIE rates across different care settings demonstrates that there is a large gap in interoperability capabilities. These interoperability capability gaps in key settings, such as behavioral health and long-term care, will be a barrier to building successful APMs. The inability to exchange data across different stakeholder groups within the care continuum hinders the ability for standardized assessment of the quality of care. For example, organ procurement organizations coordinate the exchange of transplant organs from donors to recipients. However, there is no centralized point of data collection to measure key metrics to help improve the efficiency of the transplant system.²²⁶

Priority Target Area: Privacy and Security

Lack of Clear Rules for Data Not Subject to HIPAA Privacy Protections

Often, health-related data not subject to HIPAA lacks clear legal privacy protections. These gaps in HIPAA coverage may not be readily apparent to providers and patients, as they may not understand the scope of what entities and data are covered by HIPAA.²²⁷ This can lead to patients consenting to share their data without full comprehension of how it will be used or monetized.^{228,229} For example, health data sent to a third party that is not the business associate of, owned by, or affiliated with a covered entity would likely put that data outside of the protections of HIPAA. This confusion often impacts the electronic exchange

of health information. The exchange of health data with entities not subject to HIPAA is expected to increase with the finalization of the ONC Cures and CMS Interoperability regulations. To more fully protect health information, some stakeholders have called for the establishment of a new federal entity that would have jurisdiction over traditional healthcare actors and new entrants, such as app developers.²³⁰

Lack of Control over Sharing and Disclosure of Information

Providers and patients continue to experience constraints on their ability to choose whether to electronically exchange sensitive data that are subject to redisclosure or other restrictions by state and federal privacy laws. For example, the requirement to obtain explicit patient consent to disclose data covered by 42 CFR Part 2 is often cited by providers as a barrier to sharing this sensitive data.²³¹ In addition, when patients are given the opportunity to consent to the exchange of their data it is often a global decision to participate or not, with no ability to choose which types of data are exchanged or which providers can access the data. Some providers are concerned that giving patients increased control over the availability and use of their data will put patient safety at risk and create liability for providers. For instance, a patient could decide not to allow certain data to be shared, thereby impacting a provider's clinical decision regarding the care of the patient.²³² The HITAC has noted that consensus is lacking on what data may be restricted by the patient and what data must be transmitted to support safe coordinated care.²³³ These challenges will continue to arise as providers seek to exchange and use new data types in their practice, such as SDOH data and PGHD.

It is unclear whether SDOH data can be shared or received from community service organizations, which typically are not HIPAA covered entities. If these data are generated by a community service organization, consent may not be required; therefore patients may not have knowledge of how captured data will be disclosed.²³⁴ Once SDOH data are collected, it will only be valuable if actionable connections or data exchange to and from community service organizations can be created. CIEs and some HIEs have developed trust and legal structures that facilitate the exchange of SDOH data between healthcare providers and community services organizations. However, coverage is limited.²³⁵

Similar to SDOH data, PGHD can be covered by HIPAA in certain circumstances but fall outside of these protections in others. Some patients have privacy and security concerns that make them unwilling to share PGHD with their providers. Patients need more detailed information about the use of their PGHD so they can make informed choices about what data they wish to share and with whom. Security and privacy protections that apply to PGHD are fragmented and do not have a clear regulatory framework.²³⁶

The new certification criteria that support the sharing of data via third-party apps will help advance the use of data segmentation, but adoption of this capability by the industry is not yet widespread. Consent capture is not a common data element in EHRs or third-party apps.

Lack of Clarity on the Effect of International Regulations on U.S. Healthcare Data Exchange and Access

International regulations, such as the GDPR, require many U.S. healthcare entities to comply with additional privacy requirements.²³⁷ The interplay between U.S. federal and state privacy laws and the GDPR has caused uncertainty for healthcare entities. For example, the GDPR established the "right to be forgotten" that mandates that an individual can withdraw consent for his/her data use, and an organization must erase all data related to that individual and demonstrate records of this action.²³⁸ This

right is not included in HIPAA; therefore, U.S. healthcare entities to whom the GDPR applies must ensure that their health IT systems comply with this additional layer of requirements.

Variability of Information Sharing Policies among States

States often regulate when a provider may access and disclose patient health information and to whom the information may be disclosed.²³⁹ Variability among state laws that protect the privacy of health information and can be stricter than HIPAA for the use and disclosure of data creates confusion among exchange partners and differing interpretations of how to comply with the laws. For instance, state laws differ on whether patient authorization or consent is needed before sharing the patient's data.²⁴⁰ In addition, some HIEs have policies that require patient authorization or consent that extend beyond state law. Providers that operate in multiple states may default their privacy policies to those in the state with the most restrictive policies to minimize legal risk and reduce administrative complexity.²⁴¹ Inconsistency in federal and state policies for disclosing health information (i.e., what data has additional restrictions and what steps must be taken before disclosing the data) make it difficult and expensive for health IT to support the varying policy requirements that must be met before sharing data.^{242,243}

New Technological Capabilities to Re-Identify De-Identified Data

Under HIPAA, when data are de-identified, there should be no possibility that the identities of the individuals can be re-connected to the data set.²⁴⁴ However, artificial intelligence technologies have demonstrated the ability to re-identify data that is considered de-identified under HIPAA regulations.²⁴⁵ This new technological milestone demonstrates a gap between federal privacy regulations and current industry capabilities. There is a perceived, and maybe real, lack of transparency to patients about how their de-identified data are used today, so patients may not even know that their data are at risk of being re-identified.²⁴⁶ Due to the increased ease of re-identifying de-identified data, increased public education may be needed to improve patients' awareness of how their de-identified data are being shared and used.

Challenges in the Adoption of Cybersecurity Framework(s)

In addition to HIPAA compliance, implementing a cybersecurity framework is critical to ensuring a robust security program.²⁴⁷ Supplying the resources needed to adopt and update cybersecurity frameworks continues to challenge the healthcare sector, especially for small- to medium-sized entities. Tension exists within the healthcare sector between providing time-sensitive patient care and facilitating a strong cybersecurity framework.²⁴⁸

Even with strong infrastructure in place, cybersecurity challenges persist. Attack methods continue to evolve and diversify in their point of infiltration.²⁴⁹ Frequently, when a healthcare entity is attacked, it may not identify that a breach has occurred until months later.²⁵⁰ As healthcare becomes more innovative in its use of health IT, cybersecurity risks will continue to grow. Providers will need to include additional security measures for patient portals, mobile applications, and other devices into their infrastructure.

Priority Target Area: Patient Access to Information

Limited Accessibility and Usability of Patient Portals (and Other Patient-Facing Technology)

Patient portals have become more accessible to patients, but most portals are siloed and tethered to a specific hospital or practice. While this approach offers some convenience for patients, they may struggle to manage multiple portals to access and aggregate their data. Patient portals and other patient-facing technology such as mobile apps have demonstrated challenges with user interfaces. For example, lab

results may be displayed in a manner that patients with low health literacy cannot easily understand and some portals lack accessibility support for individuals with disabilities.^{251,252} Some portals offer advanced capabilities such as telehealth functions, online scheduling options, and the ability to access physician notes, but these more advanced features are not yet widely implemented or adopted.²⁵³

As the technology for patient portals improves, many portals can now be accessed through mobile devices. It is anticipated that proposed requirements in the Cures Act NPRM and the new requirement to provide patient-facing APIs in the Promoting Interoperability programs and MIPS will simplify the process for patients to access and aggregate their data from multiple portals.

Access to Patient Data Remains Highly Fragmented from the Patients' Perspective

Patients face a burden of obtaining their data from multiple providers and their various EHR developers rather than accessing it more centrally, such as via an exchange hub. Consumer-centric models for controlling the access and exchange of data have been proposed in the past, but adoption to date has been limited.^{254,255} The new patient-facing API requirements may help simplify the process for patients to connect to a central hub to control the exchange of their data. In addition, some stakeholders have suggested that ONC ensure TEFCA provides a mechanism by which patients can request access to their data without the intervention of a provider.²⁵⁶

Ensuring Compliance around API Use

The use of APIs to give patients and the third-party apps of their choosing access to patients' data is a new development in healthcare. Health IT developers and providers are still working through how to comply with the new regulatory requirements in the Promoting Interoperability programs and MIPS. Due to the early stage of deployment of these APIs, there is limited data on how they are being implemented in the field. Multiple efforts are underway to develop guidelines and trust frameworks to support consumer-mediated exchange via APIs. The CARIN Alliance has established a code of conduct for third-party mobile apps that supports consumer-mediated exchange to address privacy concerns about healthcare data access, exchange, and use.²⁵⁷ Xcertia has created guidelines to support the safe and effective development of mobile health apps.²⁵⁸ Organizations including Ranked Health and PsyberGuide are reviewing and ranking healthcare apps to help patients and providers adopt clinically proven and high-quality digital health solutions.^{259,260} It will be important to assess developments in this space to identify any challenges that arise with patients and their third-party apps accessing their data through APIs.

Barriers to Use and Sharing of PGHD

While the adoption of PGHD has increased in recent years, patients still face a variety of challenges to sharing their PGHD with their providers.²⁶¹ Many provider organizations lack the technical infrastructure, functional workflows, and workforce capacity to receive and use the data. Many patients do not understand the value of capturing and sharing PGHD with providers.²⁶² The GAO found that of individuals who accessed their medical record online, less than five percent transmitted their health record data to a service or app.²⁶³

Providers have concerns that accepting PGHD will result in a large influx of information that will disrupt their normal workflows and add to their workload.²⁶⁴ Providers also have concerns about the reliability and quality of PGHD and worry that using inaccurate PGHD to make a clinical decision could result in a liability risk for them.

Recommendations for Addressing Health IT Infrastructure Gaps

The Cures Act requires the annual report to include recommendations for addressing the identified gaps in policies and resources across the priority target areas for achieving the ONC objectives and benchmarks and for furthering interoperability throughout the health IT infrastructure. The HITAC offers the following suggestions for HITAC activities that could result in future recommendations that would be transmitted to the National Coordinator for Health IT. Within each priority 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, while longer-term opportunities are anticipated to begin in three or more years.

Priority Target Area: Interoperability

Immediate Opportunities

Opportunity: Enable easier integration and use of data received from outside sources.

Providers often struggle to integrate data from outside sources into their workflow, while patients often struggle to integrate data from various sources into a usable longitudinal health record. The Cures Act NPRM and TECCA are anticipated to significantly impact the amount of data that will be available from outside sources.

Recommended HITAC Activity: Review and make recommendations on best practices for how health IT developers and providers can integrate and use data received from outside sources, including addressing data accuracy.

Opportunity: Offer guidance about the role of health IT in improving price transparency.

Many significant questions remain regarding how HHS should best address improving price transparency across the healthcare ecosystem.

Recommended HITAC Activity: Offer ideas for the role of health IT in improving price transparency of healthcare services.

Opportunity: Increase understanding of the challenges of integration of UDI data.

While EHRs include a field to capture UDI data, the use of this field is inconsistent. Gaining a better understanding of the challenges providers face in integrating the capture of UDI data into their workflow could help address this gap.

Recommended HITAC Activity: Convene a hearing to understand trends related to UDI data integration and understand its effect on various workflows (e.g., clinical, administrative, research, and patient).

Opportunity: Establish a framework for the use of health data made available electronically for research purposes.

Researchers have an increased interest in using health data made available electronically for research purposes; however, many barriers to achieving interoperability between these research and non-research systems persist. Clarification is needed on issues of consent, data ownership, and access.

Recommended HITAC Activity: Review and make recommendations about ONC's role in setting guidelines for the use of health data made available electronically for research purposes.

Longer-Term Opportunities

Opportunity: Improve and accelerate the use of health IT to respond to the opioid crisis.

Health IT has a key role to play in responding to the opioid crisis. HHS can improve and accelerate existing work to integrate EHRs with PDMPs and better incorporate best practices for opioid prescribing into provider workflows through clinical decision support tools.

Recommended HITAC Activity: Encourage the adoption of standards to support data segmentation by identifying policy needs and functional requirements to address patient privacy and provider needs.

Recommended HITAC Activity: Identify opportunities to use TEFCA to enable the exchange of data necessary to support the response to the opioid crisis.

Opportunity: Improve patient matching.

A variety of new methods are being adopted and used to improve patient matching. The HITAC has the opportunity to review these new approaches and raise awareness of successes and persistent challenges.

Recommended HITAC Activity: Hold hearings to explore how new and emerging technology, such as machine learning and referential matching, are improving patient matching, and develop recommendations to inform ONC's patient matching strategy in light of the findings.

Opportunity: Develop and adopt standards for SDOH data collection, transfer, and integration for population health and individuals' needs.

The collection, transfer, and integration of SDOH data collection is fragmented and varies significantly. Expanding the use of standards for non-health data presents an opportunity to integrate health and social support systems in healthcare delivery.

Recommended HITAC Activity: Continue to review and recommend SDOH data elements for inclusion in the USCDI framework and promote continued SDOH standards development.

Recommended HITAC Activity: Review opportunities for HHS to require the use of standardized psychological, social, and behavioral data across agency programs.

Opportunity: Increase transparency of EHR-related adverse patient safety events.

EHRs can pose new patient safety risks due to usability challenges. There is currently no centralized, transparent repository of these events. Addressing this need is important for enabling patient and provider education on patient safety incidents.

Recommended HITAC Activity: Develop recommendations on ways ONC can include EHR-related patient safety events in the EHR Reporting Program as required in the Cures Act.

Opportunity: Improve the electronic data exchange capabilities of behavioral health and long-term care providers.

Behavioral health and long-term care providers have lower rates of adoption of EHRs and of use of HIEs compared to eligible hospitals and clinicians. Addressing this gap is important for enabling behavioral health and long-term care providers to successfully participate in APMs.

Recommended HITAC Activity: Review and recommend steps for ONC to improve the ability of behavioral health and long-term care providers to electronically exchange data.

Priority Target Area: Privacy and Security

Immediate Opportunities

Opportunity: Increase transparency and patient education for business practices and other potential uses not covered under HIPAA.

Large amounts of health data are collected by entities not subject to HIPAA. Educating patients on the limits of federal privacy laws presents an opportunity for them to make more informed decisions about how they share their health data.

Recommended HITAC Activity: Convene a HITAC workgroup to review and provide recommendations about federal agencies' activities addressing third-party access to health data.

Recommended HITAC Activity: Identify educational approaches, technological mitigators, and potential regulatory solutions that offer improved transparency of privacy protections outside the purview of HIPAA.

Recommended HITAC Activity: Develop recommendations for additional steps for HHS and industry to take to enhance education about the requirements and applicability of HIPAA, 42 CFR Part 2, and FERPA.

Recommended HITAC Activity: Help ONC identify and define policy needs and functional requirements for data segmentation for patients, providers, and other stakeholders.

Opportunity: Improve the capabilities of health IT to electronically capture, store, and share consent information.

Health data exchange continues to increase; therefore, integrating consent functionality into health IT will allow patients to have more agency over how their data are exchanged.

Recommended HITAC Activity: Identify and suggest how consent should be captured under TEFCA.

Opportunity: Facilitate more exchange of SDOH data between healthcare providers and community service organizations and more patient education about consent.

The exchange of SDOH data is growing but additional privacy considerations still remain.

Recommended HITAC Activity: Review the consent policies and data use agreements of early adopters of SDOH data exchange (i.e., HIEs, CIEs) to develop best practices for other healthcare entities looking to exchange SDOH data.

Opportunity: Identify emerging concerns related to provider-directed and patient-managed PGHD creation and use.

The adoption and exchange of PGHD are growing but additional privacy and security considerations remain.

Recommended HITAC Activity: Review actions already underway regarding the management of and processes for protecting the privacy and security of PGHD.

Opportunity: Increase knowledge of the impact of international regulations affecting the U.S. healthcare system.

Some international regulations, such as the GDPR, require affected U.S. healthcare entities to comply with additional privacy requirements beyond those of U.S. regulations.

Recommended HITAC Activity: Identify educational approaches that offer increased transparency for international regulations (such as the GDPR) that affect the U.S. healthcare system.

Longer-Term Opportunities

Opportunity: Increase the alignment of data sharing policies across states.

There is a broad spectrum of data sharing policies across states. Aligning these policies will reduce confusion among entities involved in interstate health information exchange.

Recommended HITAC Activity: Review and make recommendations about the federal role in setting guidelines across states for the exchange of data.

Recommended HITAC Activity: Collaborate with NCVHS on its proposed revisions to HIPAA to consider strategies for aligning policies across states.

Opportunity: Increase awareness of technological capabilities to re-identify de-identified data.

Improving education about how new technological capabilities and federal privacy laws affecting de-identified data interact will increase understanding of how data may be used.

Recommended HITAC Activity: Identify additional steps HHS, providers, and other industry stakeholders should take to increase awareness about how de-identified data are used today and about the ability of new technological capabilities to re-identify de-identified data.

Recommended HITAC Activity: Convene a listening session to assess the development of technologies that prevent re-identification.

Opportunity: Offer guidance to the healthcare sector on ways to improve cybersecurity preparedness.

The adoption of cybersecurity frameworks is fragmented across the healthcare sector. Providing guidance on how to improve cybersecurity presents the opportunity to improve protections against evolving and growing cybersecurity threats.

Recommended HITAC Activity: Review existing ONC cybersecurity educational resources to identify any necessary updates, revisions, or new materials that should be developed.

Recommended HITAC Activity: Hold a hearing to identify additional opportunities for the HITAC to help improve cybersecurity preparedness.

Priority Target Area: Patient Access to Information

Immediate Opportunities

Opportunity: Consider improvement to the accessibility and usability of patient portals (and other patient-facing technology).

Patient portals have become more accessible to patients, but most portals are siloed and tethered to a specific provider. Patient portals and patient-facing mobile apps continue to demonstrate challenges with user interfaces. Improving patient portals and apps would enable patients to become more engaged in their healthcare.

Recommended HITAC Activity: Assess patient portals' and patient-facing mobile apps' operational effectiveness, patient engagement, and/or patient understanding and use of data to establish measures in the future.

Opportunity: Develop an updated roadmap for patient engagement and access to data that is less dependent on providers and their EHR developers.

Patients continue to experience challenges in accessing and aggregating their data from providers and EHR developers.

Recommended HITAC Activity: Hold listening sessions of experts and representatives of stakeholder groups (including federal agencies) to identify ideas for an updated roadmap for patient access.

Opportunity: Track deployment of APIs certified to the 2015 Edition to identify gaps in API trust frameworks and offer guidance to developers and providers as needed.

As APIs certified to the 2015 Edition criteria are deployed, there is an opportunity to identify early gaps in the new regulatory requirements, OCR guidance, and existing trust frameworks that support exchange via APIs.

Recommended HITAC Activity: Assess deployment of 2015 Edition CEHRT in the field to identify any early gaps in existing API trust frameworks and OCR guidelines and develop recommendations on how to fill the gaps. Identified challenges should be analyzed to determine if the policies proposed in the Cures Act NPRM will address the issue and if additional action or guidance is required.

Recommended HITAC Activity: Suggest ideas for guidance by HHS on API use.

Longer-Term Opportunities

Opportunity: Further understand patients' experience of sharing health data with their care team and providers' business reasons and technical ability to use and share PGHD.

While adoption of PGHD has increased in recent years, patients and providers continue to experience barriers to the sharing and use of these data. Gaining more understanding of patients' and providers' experiences with sharing PGHD will allow for it to be exchanged in a more meaningful manner.

Recommended HITAC Activity: Explore patient and provider experiences with sharing and using PGHD to continue to identify best practices and gaps.

Suggestions for Additional HITAC Initiatives

The HITAC did not identify additional target areas or related HITAC initiatives as defined in the Cures Act in FY19. The HITAC will revisit this opportunity in the FY20 annual report.

Conclusion

The HITAC made significant progress in advancing interoperability, privacy and security, and patient access to information in FY19; however, work remains in these priority target areas to achieve the full potential using health IT tools to help transform the healthcare sector. In FY20, ONC and the HITAC will continue to ...**[Note: More text will be inserted after final HITAC 2020 Plan publication.]**



Appendices

Glossary

2015 Edition Health Information Technology Certification Criteria - The standards and implementation specifications that Certified Electronic Health Record Technology would need to include to, at a minimum, support the achievement of meaningful use by eligible clinicians, eligible hospitals, and critical access hospitals under the Medicare and Medicaid Promoting Interoperability and Merit-based Incentive Payment System programs when such edition is required for use under these programs.²⁶⁵

Application Programming Interface (API) - A set of tools, definitions, and protocols for building and integrating application software. It lets a product or service communicate with other products and services without needing to know how they're implemented.²⁶⁶

CDS Hooks - A technical functionality supporting clinical decision support that enables the creation of standardized places within an EHR workflow where the EHR can issue a notification that an event is occurring. This notification can be received by an external application, which in turn can return pertinent information to the EHR for display to the EHR user.²⁶⁷

Certified Electronic Health Record Technology (CEHRT) - Electronic health record technology which meets the 2015 Edition Health IT Certification Criteria and is required for use to qualify for the Medicare and Medicaid Promoting Interoperability programs and to receive a score in the Merit-based Incentive Payment System Promoting Interoperability performance category.²⁶⁸

Common Agreement - A set of terms and conditions for health information exchange between health information networks set by the RCE as required by the 21st Century Cures Act.²⁶⁹

Consolidated-Clinical Document Architecture (C-CDA) - A document standard for the transmission of structured summary data between providers, and between providers and patients. Transmitted data supports care transitions, referrals, and care coordination.²⁷⁰

Covered Entity - An individual, organization, or agency that must comply with HIPAA requirements to protect the privacy and security of health information and must provide individuals with certain rights with respect to their health information. Examples include a health plan, a health clearinghouse, or a healthcare provider who transmits any information in an electronic form in connection with a transaction for which HHS has adopted a standard.²⁷¹

Data Segmentation for Privacy (DS4P) - An HL7[®] standard that allows a provider to tag a C-CDA document with privacy metadata that expresses the data classification and possible re-disclosure restrictions placed on the data by applicable law. This standard is relevant to health information protected under 42 CFR Part 2. This standard is included as a certification criterion in the 2015 Edition Health Information Technology Certification Criteria.²⁷²

Digital therapeutics or “Digiceuticals” - The use of digital apps in a formal role in managing a condition or symptom. The digital app could be prescribed by a clinician as a standalone treatment or in conjunction with other treatments.²⁷³

Exchange Purposes - A proposed subset of payment, healthcare operations, treatment, public health and benefits determination purposes for which exchange of electronic health information would be governed under TEFCA.²⁷⁴

Family Educational Rights and Privacy Act (FERPA) - A federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.²⁷⁵

Fast Healthcare Interoperability Resources (FHIR®) Standard - An interface specification that specifies the content of the data exchanged between healthcare applications, and how the exchange is implemented and managed. The data exchanged includes clinical data as well as healthcare-related administrative, public health, and research data.²⁷⁶

Fee-For-Service (FFS) - A method in which doctors and other healthcare providers are reimbursed for each service performed.²⁷⁷

Granular - The ability to make decisions about how specific parts of a health record can be shared, as compared to an all-in or all-out approach for data exchange.²⁷⁸

Health Information Exchange (HIE) - Both the act of moving health data electronically between organizations and an organization that facilitates information exchange. HIEs may be statewide, regional, metropolitan, or organization-specific and may be privately owned or publicly funded.²⁷⁹

Health Information Network (HIN) - An individual or entity that (a) determines, oversees, or administers policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities; (b) provides, manages, or controls any technology or service that enables or facilitates the exchange of electronic health information between or among two or more unaffiliated individuals or entities; or (c) exercises substantial influence or control with respect to the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.²⁸⁰

Health Level Seven International (HL7®) - A not-for-profit, standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services.²⁸¹

Information Blocking - A practice that (a) is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and (b) if conducted by a health information technology developer, exchange, or network such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or (c) if conducted by a healthcare provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.²⁸²

Internet of Things (IoT) – The networking capability that allows information to be sent to and received from objects and devices (such as fixtures and kitchen appliances) using the Internet.²⁸³

Interoperability – Health information technology that (a) enables the secure exchange of information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (b) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and (c) does not constitute information blocking as defined in section 3022(a) of the 21st Century Cures Act.^{284,285}

Logical Observation Identifiers Names and Codes (LOINC) – A common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents.²⁸⁶

Machine Learning - The approach of building software to perform a specific task without using explicit rule-based instructions.²⁸⁷

Medical Device - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.²⁸⁸

Merit-based Incentive Payment System (MIPS) - A quality payment incentive program administered by the Centers for Medicare & Medicaid Services which ties provider reimbursement to quality and cost-efficient care. This program aims to drive improvement in care processes and health outcomes, increase the use of healthcare information, and reduce the cost of care.²⁸⁹

Minimum Required Terms and Conditions (MRTCs) - The mandatory terms and conditions that Qualified Health Information Networks voluntarily agree to follow. The Common Agreement would include the MRTCs, as well as additional required terms and conditions developed by the RCE.²⁹⁰

Patient-Generated Health Data (PGHD) - Health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.²⁹¹

Patient Matching - The process of comparing several demographic data elements from different health IT systems to determine if they refer to the same patient.²⁹²

Prescription Drug Monitoring Program (PDMP) - A statewide electronic database that tracks all controlled substance prescriptions. Authorized users can access prescription data such as medications dispensed and doses.²⁹³

Qualified Health Information Network (QHIN) - A network of organizations working together to share data to implement the Trusted Exchange Framework, having agreed to the Common Agreement.²⁹⁴

Recognized Coordinating Entity (RCE) - A governance body that will operationalize the Trusted Exchange Framework by incorporating it into a single, all-encompassing Common Agreement to which Qualified HINs will agree to abide.²⁹⁵

Social Determinants of Health (SDOH) - The conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life.²⁹⁶

Sociogenomics - An emerging field that attempts to find the genetic basis of social behavior and its evolution. Researchers are examining the role of social factors on the expression of individual genes.²⁹⁷

Title 42 of the Code of Federal Regulations, Part 2: Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2) - A federal rule first promulgated in 1975 to address confidentiality concerns about the use of substance use disorder information in non-treatment based settings, such as administrative or criminal hearings related to the patient. This law protects the confidentiality of the identity, diagnosis, prognosis, or treatment of any patient records maintained in connection with the performance of any federally assisted program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research.²⁹⁸

Trusted Exchange Framework (TEF) - A set of principles and minimum required terms and conditions for trusted exchange, as required by the 21st Century Cures Act.²⁹⁹

Unique Device Identifier (UDI) - An alphanumeric code identifies a specific medical device that may be added to relevant records such as patients' health records and insurance claim forms.³⁰⁰

U.S. Core Data for Interoperability (USCDI) - A common set of data classes that are required for interoperable exchange. The USCDI will be expanded over time.³⁰¹

Usability - The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.³⁰²

X12 Advisory Committee - An advisory committee chartered by the American National Standards Institute (ANSI) that develops and maintains electronic data interchange standards.³⁰³



Abbreviations

42 CFR Part 2 - Title 42 of the Code of Regulations, Part 2: Confidentiality of Substance Use Disorder Patient Records

API - Application Programming Interface

APM - Alternative Payment Model

C-CDA - Consolidated-Clinical Document Architecture

CCDS - Common Clinical Data Set

CCPA - California Consumer Privacy Act of 2018

CDC - Centers for Disease Control and Prevention

CEHRT - Certified Electronic Health Record Technology

CMS - Centers for Medicare & Medicaid Services

CMS Interoperability Rule - Centers for Medicare & Medicaid Services Interoperability and Patient Access Proposed Rule

CPT® - Current Procedural Terminology

CSF - Common Security Framework

Cures Act – The 21st Century Cures Act

Cures Act NPRM - 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Notice of Proposed Rulemaking

DoD - The United States Department of Defense

DS4P - Data Segmentation for Privacy Initiative

EHI - Electronic Health Information

EHR - Electronic Health Record

EPCS - Electronic Prescribing of Controlled Substances

EU - European Union

FDA - Food and Drug Administration

FERPA - Family Educational Rights and Privacy Act

FHIR® - Fast Healthcare Interoperability Resources

FTC - Federal Trade Commission

GAO - Government Accountability Office

GDPR - General Data Protection Regulation

HHS - United States Department of Health and Human Services

HIE - Health Information Exchange

HIN - Health Information Network

HIPAA - Health Insurance Portability and Accountability Act

HITAC - Health Information Technology Advisory Committee

HITRUST - Health Information Trust Alliance

HL7® - Health Level Seven International

IoT - Internet of Things

MIPS - Merit-based Incentive Payment System

MRTCs - Minimum Required Terms and Conditions

NCVHS - National Committee on Vital and Health Statistics

NIST - National Institute of Standards and Technology

OCR - Office for Civil Rights

ONC - Office of the National Coordinator for Health Information Technology

PDMP - Prescription Drug Monitoring Program

PGHD - Patient-Generated Health Data

PRO - Patient-Reported Outcomes

QHIN - Qualified Health Information Network

QTF - QHIN Technical Framework

REST - Representational State Transfer

SAMHSA - Substance Abuse and Mental Health Services Administration

SDOH - Social Determinants of Health

SSA - Social Security Administration

SUPPORT Act - Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

TEF - Trusted Exchange Framework

TEFCA - Trusted Exchange Framework and Common Agreement

UDI - Unique Device Identifier

USCDI - United States Core Data for Interoperability

VA - Department of Veterans Affairs



Resource List

HITAC Materials

[HITAC recommendations from the NPRM Task Forces \(Information Blocking, Conditions and Maintenance of Certification, Health IT for Care Continuum and USCDI\) in support of ONC's final rule for the 21st Century Cures Act](#)

[HITAC TEFCA \(Draft 2\) Task Force recommendations](#)

[HITAC FY 2018 Annual Report](#)

ONC Publications

[2019 Interoperability Standards Advisory](#)

[21st Century Cures Act: Interoperability, Information Blocking, and the ONC Certification Program Proposed Rule](#)

[API Learning Module](#)

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