Agenda

• Workgroup Scope

• Review Schedule

• FY18 Annual Report Development to Date
  » Proposed Report Structure
  » Content for Landscape Analysis
  » Content for Gap Analysis
  » Initial Recommendation Ideas

• Discussion Questions for the HITAC Full Committee
# Annual Report Workgroup Membership and ONC Staff

<table>
<thead>
<tr>
<th>Member Name</th>
<th>Organization</th>
<th>Role</th>
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<tbody>
<tr>
<td>Carolyn Petersen</td>
<td>Individual</td>
<td>Co-Chair</td>
</tr>
<tr>
<td>Aaron Miri</td>
<td>Imprivata</td>
<td>Co-Chair</td>
</tr>
<tr>
<td>Christina Caraballo</td>
<td>Audacious Inquiry</td>
<td>HITAC Committee Member</td>
</tr>
<tr>
<td>Brett Oliver</td>
<td>Baptist Health</td>
<td>HITAC Committee Member</td>
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<tr>
<td>Chesley Richards</td>
<td>Public Health Scientific Services, CDC</td>
<td>Federal Representative</td>
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<thead>
<tr>
<th>ONC Staff Name</th>
<th>Title</th>
<th>Role</th>
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<tbody>
<tr>
<td>Donald Rucker</td>
<td>National Coordinator for Health Information Technology</td>
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<tr>
<td>Elise Sweeney Anthony</td>
<td>Executive Director, Office of Policy</td>
<td></td>
</tr>
<tr>
<td>Seth Pazinski</td>
<td>Division Director, Strategic Planning &amp; Coordination</td>
<td></td>
</tr>
<tr>
<td>Lauren Richie</td>
<td>Branch Chief, Policy Coordination</td>
<td>Designated Federal Officer (DFO)</td>
</tr>
<tr>
<td>Michelle Murray</td>
<td>Senior Health Policy Analyst</td>
<td>Workgroup ONC Staff Lead</td>
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Workgroup Scope

• **Overarching:** The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the HHS Secretary and Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.

• **Detailed:** Provide specific feedback on the content of the report as required by the 21st Century Cures Act including:
  
  » Analysis of HITAC progress related to the 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
  
  » Ideas for potential HITAC activities to address the identified gaps
HITAC Priority Target Areas noted in Section 4003 of the 21st Century Cures Act cover the following areas:

• Interoperability – Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information

• Privacy and Security – The promotion and protection of privacy and security of health information in health IT

• Patient Access – The facilitation of secure access by an individual and their caregiver(s) to such individual’s protected health information

• Any other target area related to the above target areas that the HITAC identifies as an appropriate target area to be considered on a temporary basis with adequate notice to Congress
# Meeting Schedule for Workgroup

<table>
<thead>
<tr>
<th>Month</th>
<th>Deliverables to Review</th>
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<tbody>
<tr>
<td>June 20, 2018</td>
<td>Workgroup scope for FY18 Annual Report announced</td>
</tr>
<tr>
<td>August 2, 2018</td>
<td>Discuss plans for FY18 Annual Report</td>
</tr>
<tr>
<td>August 24, 2018</td>
<td>Landscape Analysis Outline</td>
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<tr>
<td></td>
<td>Gap Analysis Outline</td>
</tr>
<tr>
<td>September 20, 2018</td>
<td>Landscape Analysis and Gap Analysis Discussion</td>
</tr>
<tr>
<td>October 18, 2018</td>
<td>Landscape Analysis and Gap Analysis Discussion</td>
</tr>
<tr>
<td></td>
<td>Outline of HITAC Progress in FY18</td>
</tr>
<tr>
<td>November 1, 2018</td>
<td>Description of HITAC Progress in FY18</td>
</tr>
<tr>
<td></td>
<td>FY18 Annual Report Outline</td>
</tr>
<tr>
<td>December 6, 2018</td>
<td>FY18 Annual Report Draft</td>
</tr>
<tr>
<td>Winter/Spring 2019</td>
<td>FY18 Annual Report Completed as Needed</td>
</tr>
<tr>
<td>Spring 2019</td>
<td>Work begins on FY19 Annual Report</td>
</tr>
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## Review Schedule for Full Committee

<table>
<thead>
<tr>
<th>Meeting Date</th>
<th>Action Items/Deliverables</th>
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<tbody>
<tr>
<td>June 20, 2018</td>
<td>Subcommittee Charge Presented</td>
</tr>
<tr>
<td>September 5, 2018</td>
<td>Workgroup Update</td>
</tr>
<tr>
<td>October 17, 2018</td>
<td>Landscape Analysis and Gap Analysis Update</td>
</tr>
<tr>
<td>November 14, 2018</td>
<td>Description of HITAC’s Work in FY18 Reviewed</td>
</tr>
<tr>
<td>January 23, 2019</td>
<td>FY18 Annual Report Reviewed</td>
</tr>
</tbody>
</table>
| Winter/Spring 2019      | FY18 Annual Report Approved by HITAC  
                          | FY18 Annual Report Submitted to HHS Secretary                                               |
                          | FY18 Annual Report Submitted to Congress                                                    |
Proposed FY18 Annual Report Structure

I. Executive Summary

II. Overview

III. HITAC Progress in FY18

IV. Health IT Infrastructure Landscape Analysis

V. Health IT Infrastructure Gap Analysis

VI. Recommendations for Addressing Health IT Infrastructure Gaps

VII. Suggestions for Additional HITAC Initiatives

VIII. Conclusion

IX. Appendices
Content for Landscape Analysis
Proposed Landscape Analysis Structure

- **Overview**
  - Legislative Requirements
  - Current ONC and HITAC Priorities

- **For Each Priority Target Area:**
  - Background
  - Current State
    - Describe Recent Advancements for Various Topics
    - Provide Examples from Stakeholder Groups
Landscape Analysis: Interoperability

• **Current State Topics and Advancements**
  
  » Existing exchange efforts including Direct Trust, Health information Exchanges (HIEs), vendor networks, Consolidated Clinical Document Architecture (C-CDA)
  
  » ONC’s proposed regulation covering open APIs, information blocking, and other health IT topics
  
  » Draft Trusted Exchange Framework
  
  » Standards and implementation specifications to support priority uses of health IT
    
    – U.S. Core Data for Interoperability (USCDI)
    
    – Interoperability Standards Priorities
    
    – HL7’s Fast Healthcare Interoperability Resources (FHIR) standard for transferring electronic medical records
Landscape Analysis: Privacy and Security

- **Current State Topics and Advancements**
  - OAuth 2.0 security profiles for authentication
  - Privacy and security protections for patient-generated health data, remote monitoring data, and other telehealth data
  - User-controlled mental health and behavioral health information sharing
    - Interoperability frameworks such as CareQuality
    - Health IT activities that address opioid epidemic and social determinants of health
    - HHS Office for Civil Rights (OCR) consumer and provider guidance for mental health and behavioral health
    - Substance Abuse and Mental Health Services Administration (SAMHSA) guidance for 42 CFR part 2
Current State Topics and Advancements (continued)

- Privacy and security concerns arising from increased health information sharing for research purposes
  - For example, Apple ResearchKit, PatientsLikeMe, 23andMe, and the NIH All of Us Research Program

- Improved patient matching and verification
  - HHS PCOR Patient Matching, Aggregating and Linking (PMAL) Project and many other efforts

- Disaster planning for health IT
  - HHS HIPAA Security Risk Assessment tool
• **Current State Topics and Advancements**
  
  » Blue Button initiatives
    
    – MyHealthEData at CMS
  
  » Data collection using mobile/wearable devices
    
    – FDA pre-certification program
  
  » Use and sharing of patient-generated health data
    
    
    – Changes to Current Procedural Terminology (CPT®) code set to support telehealth
Current State Topics and Advancements (continued)

- Use and sharing of social determinants of health data
  - Efforts to standardize data capture using Logical Observation Identifiers Names and Codes (LOINC)
  - Efforts to address health inequities

- Emerging platforms for data sharing by patients and caregivers
  - For example, Apple HealthKit and OpenNotes
Content for Gap Analysis
Proposed Gap Analysis Structure

• For each priority target area:
  » Gaps Identified
  » Opportunities Identified
• **Gaps Identified by Workgroup**

  » Ongoing efforts regarding open APIs, information blocking, Trusted Exchange Framework, and standards and implementation specifications
  
  » Lack of knowledge about user experience of health information exchange
  
  » Unmet needs of additional care settings and stakeholder groups
  
  » Delay in timeliness between issuance of guidelines and development of technology
  
  » Need to increase level of interoperability
  
  » Need to improve data quality, provenance, and usefulness
  
  » Infrastructure needs of stakeholder groups, especially broadband access
Opportunities Identified by Workgroup

» Establish usability metrics for health information exchange

» Expansion of priority use cases to meet needs of additional care settings and stakeholder groups

» Address alignment of timeliness of guidelines and development of technology

» Incentives for change across stakeholder groups to improve level of interoperability and data quality

» Support for increased broadband access across stakeholder groups, especially underserved populations
• Opportunities Identified by Workgroup (continued)

  » Continue to improve patient matching when sharing data

  » Address “reality gap” between perception of what certification requires and its operationalization

    – For example, continued mapping of Common Clinical Data Set via C-CDA and FHIR standards required when integrating networks and sharing data among smaller providers who may lack resources
• **Gaps Identified by Workgroup**

  » Variability of information sharing policies across states
    
    - Implications of the California Consumer Privacy Act of 2018; for example, what happens if other states pass similar legislation?
  
  » Lack of knowledge about HIPAA and Confidentiality of Substance Use Disorder Patient Records (a.k.a. 42 CFR Part 2) regulation implications
  
  » Lack of user control to share and disclose information
  
  » Implications of European Union’s General Data Protection Regulation (GDPR) and Privacy Shield
  
  » Variability in adoption of cybersecurity framework(s)
    
    - For example, health care organizations concerned about being held liable for breach of data at a vendor
  
  » Lack of user awareness and education about privacy and security settings
  
  » Implications of emergence of the Internet of Things (IoT)
• **Opportunities Identified by Workgroup**
  
  » Increased uniformity of information sharing policies across states
    
    - Address implications of the California Consumer Privacy Act of 2018
  
  » Education about HIPAA and Confidentiality of Substance Use Disorder Patient Records (a.k.a. 42 CFR Part 2) regulation implications
  
  » Granular levels of consent to share and disclose information
  
  » Address implications of European Union’s General Data Protection Regulation (GDPR) and Privacy Shield
  
  » Support for widespread adoption of cybersecurity framework(s)
  
  » Education of technology users about privacy and security settings, especially for social media
  
  » Consider what to regulate about the Internet of Things (IoT)
  
  » Continue to improve patient matching when sharing data
Gaps Identified by Workgroup

- Lack of patient and caregiver access to patient data
- Use and sharing of patient-generated health data (PGHD) and other data from mobile devices
- Need to improve alignment of timing of planning activities with operational impact of technology development
- Potential for lack of net neutrality due to market forces
- Unmet infrastructure needs for underserved populations
- Accessibility and usability of patient portals and other patient-facing technology continue to need improvement
- Patient awareness and education about health IT resources
Opportunities Identified by Workgroup

- Support use of APIs to improve access to patient data
- Consider workflow and technology improvements to increase use and sharing of PGHD and other data from mobile devices
  - For example, impact of clinical grade data collected by patients on testing costs
- Better align timing of planning activities with operational impact
- Consider implications of varying experiences with net neutrality at national, state, and local levels
- Support infrastructure needs for underserved populations, including exchange costs, prevalence of electronic equipment, internet access, availability of pharmacy services, and use of telehealth services
• Opportunities Identified by Workgroup (continued)
  » Consider improvements to accessibility and usability of patient portals and other patient-facing technology
  » Encourage patient and caregiver education about health IT resources
  » Address “reality gap” between perception of what has been certified for a system and what is truly interoperable in the field
Initial Recommendation Ideas
Proposed Recommendations Section Structure

• For each priority target area:
  » Recommendations for Addressing Gaps and Opportunities
**Recommendation Ideas: Interoperability**

- **Potential Activities Identified by Workgroup to Date**
  
  » **Opportunity:** Address “reality gap” between perception of what has been certified for a system and what is truly interoperable in the field
    
    - For example, continued mapping of Common Clinical Data Set via CCD-A and FHIR standards required when integrating networks and sharing data among smaller providers who may lack resources to upgrade their systems
    
    - HITAC Activity Idea: Further measure whether systems are truly interoperable at both content and transport levels after implementation, especially among smaller providers
Recommendation Ideas: Privacy and Security

• Potential Activities Identified by Workgroup to Date

  » Opportunity: Increased uniformity of information sharing policies across states
    – Address implications of the California Consumer Privacy Act of 2018
    – HITAC Activity Idea: Consider federal role in setting guidelines for exchange of data across states

  » Opportunity: Support for widespread adoption of cybersecurity framework(s)
    – HITAC Activity Idea: Consider whether a nationwide cybersecurity framework should be adopted
    – HITAC Activity Idea: Delineate cybersecurity accountability for data by role
Recommendation Ideas: Patient Access to Information

• Potential Activities Identified by Workgroup to Date

  » Opportunity: Support use of APIs to improve access to patient data
    – ONC and CMS already raising awareness of value of use of APIs

  » Opportunity: Support infrastructure needs for underserved populations, including exchange costs, prevalence of electronic equipment, internet access, pharmacy services, and use of telehealth services
    – HITAC Activity Idea: Measure impact of monetization of exchange of data
Potential Activities Identified by Workgroup to Date (Continued)

» Opportunity: Consider improvements to accessibility and usability of patient portals and other patient-facing technology
  – HITAC Activity Idea: Measure amount/length of time a portal has been online and working properly, patient engagement and/or patient understanding of data

» Opportunity: Encourage patient and caregiver education about health IT resources
  – HITAC Activity Idea: Identify use cases demonstrating value of patient’s data to the patient
Discussion Questions for the HITAC Full Committee

• Do you have any suggestions for the current state topics and advancements listed in the landscape analysis?
• Do you have any suggestions for the gaps and opportunities listed in the gap analysis?
• What recommendations would you suggest for HITAC activities that would address the gaps and opportunities?

» Please note that the workgroup will continue their discussion about recommendation ideas at their meeting on October 18.
Questions?