

## HITAC Annual Report for Fiscal Year 2019

### List of HITAC Members' Comments

The Annual Report Workgroup collected comments from HITAC members on the version of the draft annual report dated 1/15/20 and convened to propose solutions for each comment, as noted below.

Section	Subsection	Page	HITAC Member(s)	Original Language	HITAC Member Suggestion	Proposed Solution
<b>Executive Summary</b>						
Health IT Infrastructure Landscape	Priority Target Area: Patient Access to Information	2	Cynthia Fisher	"Continued information and education, improve 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."	"Continued information and education, improve accessibility, <b>price transparency</b> , 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."	No change was made. Rationale: Information about health care costs doesn't make patients and providers more aware of the benefits of health IT.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Interoperability; Immediate Opportunities, Key Gap: Lack of Price Transparency	3	Cynthia Fisher	Key Opportunity: "Offer guidance about the role of health IT in improving price transparency"	<del>"Offer guidance about the role of health IT in improving price transparency"</del> <b>Leverage ONC authority and health information technology to deliver real price transparency"</b>	No change was made. Rationale: The HITAC is an advisory committee appointed to offer guidance. It has no oversight or reporting function with regard to ONC.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Interoperability, Immediate Opportunities, Key Gap: Lack of Price Transparency	3	Cynthia Fisher	Recommended HITAC Activity: "Offer ideas for the role of health IT in improving price transparency of healthcare services"	<del>"Offer ideas for the role of health IT in improving price transparency of healthcare services"</del> <b>Review existing EDI and related standards and practices for billing and financial data sharing and leverage this experience to develop efficiencies in promoting real transparency for patients and employers in order to support a free marketplace for healthcare services"</b>	No change was made. Rationale: The HITAC is an advisory committee that has neither the authority nor the resources to undertake independent research on its own, and no authority or infrastructure to compel healthcare industry stakeholders to implement the results of such research.
Health IT Infrastructure Gaps,	Priority Target Area: Interoperability,	4	Ken Kawamoto		Added corresponding gap, opportunity and recommend HITAC activity based on the suggested topic	Change was made.



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Opportunities and Recommendations Table	Immediate Opportunities, Key Opportunities	(also see pp.37 and 42)			of limited support for restricting the scope of data shared with third parties via FHIR	Rationale: AR Workgroup agrees that this gap should be addressed in this report.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Interoperability, Longer-Term Opportunities, Key Gap: Need for improved patient matching when sharing data	3  (also p.40)	Denise Webb	Key Opportunity: "Improve Patient Matching"	Comment: "I suggest we move this to immediate opportunities given the passage of the recent budget bill that includes a directive calls for HHS to report back within one year on the effectiveness of current methods and recommend actions that increase the likelihood of an accurate match of patients to their healthcare data, which can include a standard for a unique patient health identifier."	Change was made. Rationale: Initial discussion by the HITAC on 1/15/20 showed interest in this adopting this suggestion, and the Annual Report Workgroup concurs.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Interoperability, Longer-Term Opportunities, Key Gap: EHR-related adverse patient safety events	3  (also p.40)	Denise Webb	Key Opportunity: "Increase transparency of EHR-related adverse patient safety events"	Comment: "What is the current timeframe for ONC's work on the EHR Reporting Program as it was deferred last year? If it is this year, suggest we move this up to immediate opportunities."	Change was made. Rationale: Initial discussion by the HITAC on 1/15/20 showed interest in this adopting this suggestion, and the Annual Report Workgroup concurs. The EHR Reporting Program is part of the HITAC 2020 Plan.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Interoperability, Longer-Term Opportunities	3	Terry O'Malley		Add row Key gap: "Standards for metadata" Key Opportunity: "Establish common nomenclature and use" Recommended HITAC Activity: "Convene a HITAC workgroup to review and provide recommendations regarding metadata standards and potential additions to USCDI"  Comment: "Many data management tasks are burdensome because they are manual and require humans to	No change was made. Rationale: This suggestion has been placed on the list of potential topics for consideration for the FY20 annual report.



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					<p>identify when a data element is an old version, a duplicate or from a dubious source. Metadata will enable many of these tasks to be performed by machines with humans left to reconcile the differences that the machines have identified (rather than having the humans identify the differences).</p> <p>“I propose a task force to do a deep review of prior work on metadata (which has been extensive) and make recommendations regarding the use of metadata for burden reduction.”</p>	
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Privacy and Security, Immediate Opportunities, Key Gap: Lack of control over sharing and disclosure of information	4	Terry O’Malley	Key Gap: “Lack of control over sharing and disclosure of information”	<p>Comment: “Several interrelated issues: Re-use of data after ‘release’ by patient without clarity around implications of sharing data; is it really ‘consent’ if it’s not clear?; regulations to control reuse; clarity around who has authority to consent to release (part of the issue of who has authority to consent to treatment). How are these different types of consent captured, shared and enforced? What happens if they are not?”</p> <p>AR Workgroup modification: New gap: “Lack of clarity about the parameters of data sharing and disclosure and their implications for consent”</p> <p>Retain existing opportunity and recommended HITAC activity addressing consent.</p>	Change was made. Rationale: Create a new gap for consent, separate from the gap about “lack of control” with the SDOH and PGHD opportunities. Also add consent concerns to the list of potential topics for FY20.
Health IT Infrastructure Gaps,	Priority Target Area: Privacy and Security,	4	Terry O’Malley	Recommended HITAC Activity: “Identify and suggest how	Comment: “Consent: I recommend a specific task force to address the complexities of ‘Consent’. There is	Change was made. (See related gap above.)



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Opportunities and Recommendations Table	Immediate Opportunities, Key Gap: Lack of control over sharing and disclosure of information			consent should be captured under TEFCFA”	no uniform consent process nor is there a uniform consent standard because health information users are heterogeneous and there are hundreds of specific information requests.  “Further complexity derives from the intersection of DS4P, merged clinical/research/administrative data use consents, the growing ability to ‘re-identify’ de-identified data. No one process is likely to address the range of issues generated by the current process. My concern, however, is to protect a subgroup of patients who do not read (or understand ‘consent’ as presented currently) it might be reasonable to consider creating a basic consent ‘form’ that specifies restricted data use that can then be expanded by the individual, essentially specifying a limited ‘opt-in’ standard.”	Rationale: Create a new gap for consent, separate from the gap about “lack of control” with the SDOH and PGHD opportunities. Also, add consent concerns to the list of potential topics for FY20.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Privacy and Security, Immediate Opportunities, Key Opportunities, Key Gap: Lack of control over sharing and disclosure of information	4	Denise Webb	Key Opportunity: “Facilitate more exchange of SDOH data between healthcare providers and community service organizations and more patient education about consent”	Comment: “The timeframe for this is set as immediate but we have the timeframe for developing and adopting standards for SDOH above as a longer-term opportunity. Should we align these?”	Change was made. Rationale: Initial discussion by the HITAC on 1/15/20 showed interest in this adopting this suggestion to move this opportunity to the Immediate tier, and the Annual Workgroup concurs.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Privacy and Security, Longer-Term Opportunities,	5	Terry O’Malley	Recommended HITAC Activity: “Convene a listening session to assess the development of technologies that prevent re-identification”	Comment: “Prevention or punishment?”	No change was not made. Rationale: This suggestion has been placed on the list of potential topics for consideration for the FY20 annual report.



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	Key Gap: New technological capabilities to re-identify de-identified data					
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Patient Access to Information, Immediate Opportunities, Key Gap: Limited accessibility and usability of patient portals	5	Terry O'Malley	Recommended HITAC Activity: Assess patient portals' and patient-facing mobile apps' operational effectiveness, patient engagement, and/or patient understanding and use of fate to establish measures in the future	Comment: "Should 'portal managers' have HIPAA-like responsibilities for what happens to data that transits their portal?"	No change was made. Rationale: Currently, facilitators of data distribution via portals are not responsible for the content of that data
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Patient Access to Information, Immediate Opportunities, Key Gap: Access to patient data remains highly fragmented	5, 38	Cynthia Fisher	Key Gap: "Access to patient data remains highly fragmented from the patients' perspective"	"Access to patient data remains highly fragmented from the patients' perspective and is blocking innovation"	No change was made. Rationale: This statement is speculative and there is no evidence that it is the only possible outcome, rendering it potentially inaccurate.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Patient Access to Information, Immediate Opportunities, Key Gap: Access to patient data remains highly fragmented	5, 43	AR Workgroup	Key Opportunity: "Develop an updated roadmap for patient engagement and access to data that is less dependent on providers and their EHR developers"	"Develop an updated roadmap for patient engagement and access to <del>data</del> clinical information that is less dependent on providers and their EHR developers"	No change was made. Rationale: The change would unnecessarily restrict the types of data covered by the roadmap.
Health IT Infrastructure Gaps, Opportunities and	Priority Target Area: Patient Access to Information,	5, 43	Cynthia Fisher	Recommended HITAC Activity: "Hold listening sessions of experts and representatives of stakeholder groups (including federal agencies) to identify areas	"Hold listening sessions of experts and representatives of stakeholder groups (including federal agencies) to identify areas for an updated	Change was made with modification to the proposed text. Rationale: Providing patient access to financial



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Recommendations Table	Immediate Opportunities, Key Gap: Access to patient data remains highly fragmented			for an updated roadmap for patient access”	roadmap for patient access to <b>clinical and financial information</b> AR Workgroup modification: <b>“...that offers a more useful experience for patients while reducing burden on clinicians”</b>	information has been added elsewhere in the FY19 report where it is a better fit and to the list of potential topics for consideration for the FY20 annual report. The AR Workgroup agrees that clarification of patient access is needed but that limiting the types of data covered by the roadmap is unnecessary.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Patient Access to Information, Immediate Opportunities	5	Cynthia Fisher		Add Row Key Gap: <b>“Lack of Transparency in data and pricing for patient health care services”</b> Key Opportunity: <b>“Improve real-time patient access to their health data and price information for items and services in the health care services”</b> Recommended HITAC Activity: <b>“(1) Review and make recommendations regarding policies and future rulemaking that would aggregate health and price information and allow patients to access it in real time (2) Identify critical data elements necessary for the transparency of price of health care items and services prior to delivery. Help ONC determine and define policy needs and functional requirements for patient access to a “pre-adjudication explanation of benefits.”</b>	No change was made. Rationale: The topic of price transparency is now noted in this subsection in another line. It has also been added to the list of potential topics for consideration for the FY20 annual report.
Health IT Infrastructure Gaps, Opportunities and Recommendations Table	Priority Target Area: Patient Access to Information, Immediate Opportunities	5	Cynthia Fisher		Add Row Key Gaps: <b>“Price data and clinical information is not easily connected in health IT systems”</b> Key Opportunity: <b>“Improve real-time transparency into patient clinical</b>	No change was made. Rationale: The topic of price transparency is now noted in this subsection in another line. It has also been added to the list of potential topics for



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					<p>data and price information and connect clinical and financial data”</p> <p>Recommended HITAC Activity:                      “Suggest recommendations for standards that would connect price and clinical information data. Assist ONC with the identification of methods for policy making and functional requirements for health IT stakeholder adoption recommended standards.”</p>	consideration for the FY20 annual report.
<b>HITAC Progress in FY19</b>						
Health IT for the Care Continuum Task Force	Specific Charge	10	Denise Webb	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	Comment: “Fix font and color of the number (5) to match format of preceding numbered text.”	Change was made. Rationale: AR Workgroup agrees that this formatting fix is needed.
<b>Landscape Analysis</b>						
Federal Activities across the Priority Target Areas	ONC’s Regulation for the 21 <sup>st</sup> Century Cures Act, Information Blocking	14	Cynthia Fisher	“For instance, some actors are perceived as charging rates designed to deter connectivity or exchange with competing technologies or services.”	“For instance, some actors are <del>perceived as</del> charging rates <del>designed to that</del> deter connectivity or exchange with competing technologies or services.”	No change was made. Rationale: The existing text accurately portrays the landscape because disagreement remains within the healthcare community about the intent of rates charged.
Federal Activities across the Priority Target Areas	ONC’s Regulation for the 21 <sup>st</sup> Century Cures Act, Application Programming Interfaces	15	Cynthia Fisher	“ONC proposes certification requirements that would improve interoperability by focusing on standardized, transparent, and pro-competitive API practices.”	“ONC proposes certification requirements that would improve interoperability by focusing on standardized, transparent, and pro-competitive API practices <b>that would allow for real-time access to EHI.</b> ”	Change was made. Rationale: AR Workgroup agrees that this addition is fine.
Federal Activities across the Priority Target Areas	ONC’s Regulation for the 21 <sup>st</sup> Century Cures Act, United States Core Data for Interoperability (USCDI)	15	Cynthia Fisher	“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).”	“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). <b>Future updates to the USCDI should include images, such as X-rays, MRIs, and CT scans, care plans, and price</b>	No change was made. Rationale: These comments go beyond the work undertaken by the USCDI Task Force in FY19.



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					and payment data to further other ONC priorities related to patient access to data and price transparency.”	
Federal Activities across the Priority Target Areas	Other Federal Activities, Price Transparency	18	Cynthia Fisher	“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. 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.”	“In November 2019, CMS <del>announced its intention to issue a</del> <b>Final rule on</b> a price transparency <del>(<i>Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public: Final Rule</i>)</del> rule that <b>requires each hospital operating within the United States to establish, {and update,} and make public a yearly list of the hospital’s standard charges (including gross charges, discounted cash prices, payer-specific negotiated charges, and de-identified minimum and maximum negotiated charges) for items and services provided by the hospital. will address the hospital proposal from July and propose an approach to health plan price transparency.</b> CMS also issued a proposed rule on health plan price transparency <del>(<i>Transparency in Coverage: Proposed Rule</i>)</del> with the Department of Labor and the Department of the Treasury. Furthermore, <del>i</del> 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	Change was made. Rationale: AR Workgroup agrees that this update about the status of CMS’ rules is needed, along with some citations of the rules.





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					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. Finally, CMS issued a proposed rule on physician self-referral <del>Stark (Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations: Proposed Rule)</del> which that highlightse <del>d</del> the opportunity to improve price transparency and propose <del>s</del> d inclusion of price transparency requirements in exceptions under the rule.”	
Federal Activities across the Priority Target Areas	Other Federal Activities, Price Transparency	18	Cynthia Fisher		Insert: “Furthermore, it will improve inefficiencies in the healthcare market and allow innovative technology companies to provide patients, employers, and providers with the information they need to make informed choices for quality and cost-efficient care.”	No change was made. Rationale: This statement is speculative and there is no evidence that it is the only possible outcome, rendering it potentially inaccurate.
Priority Target Area: Interoperability	Background	19	Cynthia Fisher	“As of 2017, only 10 percent of office-based physicians can find, send, receive, and integrate patient health information from outside sources.”	“As of 2017, only 10 percent of office-based physicians can find, send, receive, and integrate patient health information from outside sources. We note that the information that follows in this section is simply for context and does not necessarily reflect specific discussions or actions of HITAC. “	No change was made. Rationale: This statement is superfluous and therefore unnecessary.
Priority Target Area: Interoperability	Health Information Exchange	20	Cynthia Fisher	“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.”	“As a result, i <del>ndividuals are</del> <del>burdened by have</del> ing-fragmented to access to their health information via multiple portals, and healthcare providers <del>must</del> create many costly, point-to-point interfaces to send and receive needed data.	Change was made. Rationale: The modified revision improves clarity and brevity.

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					AR Workgroup modification: As a result, <del>Individuals are burdened by having to</del> <b>must</b> access their health information via multiple portals, and healthcare providers must create many costly, point-to-point interfaces to send and receive needed data."	
Priority Target Area: Interoperability	Health Information Exchange	20	Cynthia Fisher	"Moving forward, connectivity between HIEs and nationwide organizations will be heavily influenced by the implementation of TEFCA."	<del>"Moving forward, connectivity between HIEs and nationwide organizations will be heavily influenced by the implementation of TEFCA."</del>	No change was made. Rationale: The statement notes that the implementation of TEFCA will influence connectivity without making unsubstantiated claims about how TEFCA will influence connectivity, and so is accurate as written.
Priority Target Area: Interoperability	Health Information Exchange	20	Cynthia Fisher	"However, TEFCA will expand the required reciprocity of data exchange to a much broader set of Exchange Purposes."	<del>"However, For those entities that voluntarily choose to participate in TEFCA, ONC has proposed to will</del> expand the required reciprocity of data exchange to a <del>much</del> broader set of Exchange Purposes."  AR Workgroup modification: "However, For those entities that <b>voluntarily choose to participate in</b> TEFCA, <b>ONC has proposed to will</b> expand the required reciprocity of data exchange to a <del>much</del> broader set of Exchange Purposes."	Change was made. Rationale: The modified revision improves clarity.
Priority Target Area: Interoperability	Health Information Exchange	20	Cynthia Fisher		Insert: <b>"Other options must be available to be sure innovative technologies that may provide new ways of enabling patient access and health data exchange are allowed to flourish."</b>	No change was made. Rationale: This suggested statement does not reflect discussion by the HITAC nor the expressed opinion of most members.

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Priority Target Area: Interoperability	Unique Data Identifier	20	Terry O'Malley	"HHS has taken steps to advance the capture of the UDI in EHRs, and additional measures remain under consideration.... CMS has not issued any formal decision regarding the adoption of UDI information on Medicare claims forms."	Comment: "USCDI recommendation to create a unique, persistent identifier for each data element to enable de-duplication, accurate versioning as well as provenance. Who is working on this?"	No change was made. Rationale: The question does not suggest a change to the report text.
Priority Target Area: Interoperability	Sharing Data with the Research Community	21	Cynthia Fisher	"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."	<del>"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."</del>	No change was made. Rationale: The existing statement strengthens the annual report by providing a factually accurate example of the concept expressed in the first sentence of the paragraph.
Priority Target Area: Interoperability	Sharing Data with the Research Community	21	Cynthia Fisher		Insert: "Patients should know who is accessing their data for research purposes and should be driving, and at a minimum providing consent for, the use of their information for research activities. EHR vendors, hospitals, insurance companies and others are brokering patient data for research and product development. There should be a process for patients to have full knowledge of how data is being used and have the ability to opt in or opt out of such use. Data provenance is important to support this effort." AR Workgroup modification: "The use of patient data not covered by HIPAA and without patient consent, for research or other purposes, is a growing concern." [With a cited source]	Change was made with modification to the proposed text. Rationale: This suggested text addresses the use of patient data for research and commercial purposes. Patients already must provide informed consent for use of their data for research activities subject to certain exceptions, e.g., quality improvement. The modified comment conveys the point with greater clarity and brevity while avoiding mention of issues on which HITAC members hold varying opinions, such as whether and how patients should be able to consent.
Priority Target Area: Interoperability	Health IT Support for Opioid Epidemic Response	21	Denise Webb	"For example, a clinician would receive an alert asking if he/she would like to co-prescribe	Comment: "What does co-prescribe mean? Not familiar." AR Workgroup modification:	Change was made. Rationale: Modification will clarify the existing text.



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				naloxone for patients who meet certain risk criteria as defined by the CDC Guidelines.”	Add “For example, a clinician would receive an alert asking if he/she would like to co-prescribe naloxone, <b>i.e., prescribe it in conjunction with additional medication</b> , for patients who meet certain risk criteria as defined by the CDC Guidelines.”	
Priority Target Area: Privacy and Security	State Data Exchange and Privacy Considerations	27	Denise Webb	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.	Comment: “Use the figure 8 here instead of the word for readability— numbers in a series where there is at least one over 10 can all be expressed as figures even when a figure in the series is less than 10 when referring to the same item (e.g. number of states in this example) in the series within a sentence.”	No change was made. Rationale: Kept as-is for consistency throughout the report and with the AP Stylebook’s punctuation rule to spell out numbers under 10.
Priority Target Area: Privacy and Security	State Data Exchange and Privacy Considerations	28	Denise Webb	The California Legislature is currently considering a number of amendments to CCPA to address stakeholder feedback.	Comment: “Consider using concise language, such as ‘several’ instead of ‘a number of.’”	Change was made. Rationale: AR Workgroup agrees that this change in word choice is fine.
Priority Target Area: Patient Access to Information	Patient-Controlled Data Collection, Access, and Sharing	29	Cynthia Fisher	“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.”	“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. <b>Market research has also indicated that patients generally distrust the health care system as a whole and are seeking transparency before, during, and after services are rendered. Patients express concerns about how their clinicians are recording their visits; they are not included in discussions about the diagnosis, procedure, or other codes their physician is recording and report uncertainty in the accuracy of their medical records and the subsequent bills they receive.</b>	No change was made. Rationale: The statements in this suggested paragraph are not supported by accompanying documentation. The existing text makes a broader statement that requires no citation so it has been retained as-is.

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					Patient advocates have suggested the development of tools such as projected screens that would show the patient what the physician is entering into the EHR as well as tools that would assist with understanding coding included on medical bills.”	
Priority Target Area: Patient Access to Information	Use and Sharing of Patient Generated Health Data	30	Steven Lane		Comment: Provide clarity that PGHD means both patient-reported outcomes and data generated from patient devices.	Change was made. Rationale: The Use and Sharing of PGHD section in the landscape analysis addresses both PROs and data from patient devices as types of PGHD, but was further clarified for devices.
<b>Gap Analysis</b>						
Priority Target Area: Interoperability	Lack of Price Transparency	33	Cynthia Fisher	“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.”	“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. For too long health care providers and health plans have fought to protect their interests by withholding critical information that patients need to make health decisions and that employers need to provide high quality insurance and benefits at low cost to meet their fiduciary duties. The health care industry has hid behind complexity of pricing arrangements to avoid providing important information to patients. This resistance and complexity has worked against patient interests.”	No change was made. Rationale: This statement, unsupported by documentation, represents an opinion not shared by a majority of HITAC members.



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Priority Target Area: Interoperability	Lack of Price Transparency	33	Cynthia Fisher	“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.”	Suggested that this statement be deleted.	No change was made. Rationale: The original statement was retained, and a citation has been added to support it.
Priority Target Area: Interoperability	Lack of Price Transparency	33	Cynthia Fisher	“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. The HITAC has noted a number of issues that should be considered by HHS in future rulemaking to address price transparency.”	<del>“Even when patients have</del> Current price comparison tools available today are unknown to consumers, are difficult to access, and provide estimates rather than real prices. <del>to them, they rarely use the tools.</del> Patients also need real price information, including cash prices and negotiates rates in advance of care 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. The HITAC has noted a number of issues that should be considered by HHS in future rulemaking to address price transparency.”	No change was made. Rationale: This suggested statement is unsupported by documentation and implies that providers can estimate the cost of services that they cannot foresee will be needed, which is not the case.
Priority Target Area: Interoperability	Lack of Price Transparency	33	Cynthia Fisher		Insert: “In addition, price transparency continues to be a critical issue for patients. Patients are unable to shop for high value services and cannot anticipate the prices of items and services rendered during their treatment or their potentially catastrophic out-of-	No change was made. Rationale: The suggested statements are not supported by accompanying documentation. Furthermore, patients can request estimates of costs for all but emergency treatment, though



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					pocket costs once they receive their bills. Real-time transparency into data and pricing is not an infeasible ask- industries such as financial services, transportation, and household consumer shopping have made the changes necessary to empower patients with this information they need, even when the data needs to be aggregated across multiple vendors, custodians, or other systems."	actual costs may vary if the unexpected additional services are needed. The concern about pricing was noted in the revision of the previous paragraph.
Priority Target Area: Interoperability	Lack of Price Transparency	33	Cynthia Fisher		Insert: "This is an area of great importance to the American people to allow them to shop for high value care and reduce the burden of unanticipated costs on patients and their families. Ultimately knowing prices, including cash and negotiated rates, will create a competitive and free market, lowering the cost of both care and coverage nationwide."	No change was made. Rationale: The importance of price transparency to consumers is noted in other places in this report. The assertion that the availability of prices will result in a competitive and free market that results in lower care costs is unsubstantiated, and cannot be ascertained, given that patients and providers cannot always determine what service(s) will be needed, e.g., during surgery.
Priority Target Area: Privacy and Security	Lack of Clear Rules for Data Not Subject to HIPAA Privacy Protections	36	Cynthia Fisher	"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."	<del>"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."</del>	No change was made. Rationale: It is unclear why this statement is being suggested to be removed because it is factual, accurate, and relevant.
Priority Target Area: Privacy and Security	New Gap: Limited Support for Restricting Scope of Data Shared with Third Parties via FHIR	n/a (may be placed	Ken Kawamoto		Insert: "Limited Support for Restricting Scope of Data Shared with Third Parties via FHIR "Currently, the FHIR capabilities specified by ONC regulations only provide limited support for	Change was made with modification to the proposed text. Rationale: AR Workgroup agrees that this gap should be



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		on p.37)			<p>restricting the scope of patient data shared with third parties. For example, consider the case where an ONC-certified health IT product is used by a healthcare system or patient to provide access to a patient’s cholesterol level to a third-party vendor product such as a patient-facing smartphone app. Under these current-day conditions, it is currently not possible for that health system or patient to only provide access to the cholesterol level; it must provide access to all of the patient’s laboratory data, including potentially highly sensitive data such as the patient’s HIV, syphilis, gonorrhea, and chlamydia test results. Similarly, for a healthcare system or patient using these ONC-certified products to provide access to a patient’s age and gender, it is currently not possible for that health system or patient to only provide access to the age and gender; it must provide access to all demographic data, including potentially data such as the patient’s name, race, medical record number and other external identifiers, marital status, home and cell phone number, personal and work emails, and home address.”</p> <p>AR Workgroup modification:                      “Limited Support for Restricting Scope of Data Shared with Third Parties via FHIR®                      “Currently, The FHIR® capabilities specified by ONC regulations proposed for adoption in the Cures</p>	addressed in this report with citations.



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					<p><b>Act NPRM</b> <del>only</del> provide limited support for restricting the scope of patient data shared with third parties. For example, consider the case <b>of a health system using</b> <del>where</del> an ONC-certified health IT <del>product</del> <b>module</b> <del>is used by a healthcare system or patient to provide access to a patient's</del> <b>specific lab result, e.g.,</b> cholesterol level, <del>to</del> <b>by</b> a third-party vendor product such as a patient-facing smartphone app. Under <del>these current day</del> <b>the proposed</b> conditions, it is <del>currently</del> not possible for that health system or patient to <del>only</del> provide access to <b>only</b> the <b>specific lab result</b> cholesterol level; <del>it must provide</del> access must be provided to all of the patient's laboratory data, including potentially highly sensitive data, <del>such as the patient's HIV, syphilis, gonorrhea, and chlamydia test results</del> <b>e.g., test results for sexually transmitted infections</b>. Similarly, for a healthcare system or patient using <del>these</del> <b>an</b> ONC-certified <del>products</del> <b>module</b> to provide access to a patient's age and gender, it is currently not possible for that health system or patient to <del>only</del> provide access to <b>only</b> the age and gender; <del>it must provide</del> access <b>must be provided</b> to all demographic data, including <del>potentially</del> data such as the patient's name, race, medical record number and other external identifiers, marital status, home and cell phone number, personal and work emails, and home address. <b>These challenges stem from the</b></p>	

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					current proposed FHIR® capabilities which only allow access for data sharing to be granted for an entire high-level category (i.e., observations, conditions, or medications) rather than for a specific data element within a category.”	
Priority Target Area: Privacy and Security	New Gap: Use of Synthetic Data Raises Concerns	n/a	John Kansky		Comment: “What security & privacy considerations are there driven by the emergence of "synthetic data". My working definition of synthetic data is a dataset that is derived from real data ... is statistically identical to the real data... but (allegedly) is an completely new data set that does not relate to any actual humans. The potential of synthetic data is significant. Imagine being able to conduct research, train machine learning models, etc., without the constraints of HIPAA. But the world isn't ready to understand and accept that concept and I'm unclear on the extent to which the validity of the claims has been tested and validated.”	No change was made. Rationale: This suggestion has been placed on the list of potential topics for consideration for the FY20 annual report.
Priority Target Area: Patient Access to Information	Access to Patient Data Remains Highly Fragmented from the Patient’s Perspective and May Block Innovation	38	Cynthia Fisher	“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. The new patient-facing API requirements may help	"...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. In addition, health information includes clinical and financial data; however, this data is not always linked for purposes of claims payment of patient use. The availability of clinical and price and payment information is critical and	Change was made with modification to the proposed text. Rationale: Health information is not yet well-defined, but the idea that it includes both clinical and financial information, and that standards may be needed, can be integrated into the existing text.



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				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 TEFCAs provide a mechanism by which patients can request access to their data without the intervention of a provider."	<p>there is value in developing standards to support the integration of this information."</p> <p>AR Workgroup Modification:                      "Patients face a burden of obtaining their data from <b>multiple payers, multiple providers, and their various EHR</b> 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. 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 TEFCAs provide a mechanism by which patients can request access to their data without the intervention of a provider.  <b>Additionally, there is value in developing standards to support the integration of both clinical and financial information."</b></p>	
<b>Recommendations for Addressing Health IT Infrastructure Gaps</b>						
Priority Target Area: Interoperability	Immediate Opportunities, Price Transparency	39	Cynthia Fisher	"Opportunity: Offer guidance about the role of health IT in improving price transparency.	"Opportunity: Offer <b>recommendations for policy or guidance about the role use of health IT in improving to efficiently implement real price transparency system-wide."</b>	No change was made. Rationale: The existing text is broad enough to cover this circumstance.
Priority Target Area: Interoperability	Immediate Opportunities, Price Transparency	39	Cynthia Fisher	"Many significant questions remain regarding how HHS should best address improving price	<b>"There are many opportunities</b> <del>Many significant questions remain regarding how HHS should best to address improving price</del>	No change was made. Rationale: The suggested revision offers no further information than the existing



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				transparency across the healthcare ecosystem.”	transparency across the healthcare ecosystem. <b>HHS has published rules that will go into effect on January 1, 2021. Immediate recommendations can help enable entities subject to price transparency rules to comply more efficiently.”</b>	text, and does not take into account that any ONC efforts must be coordinated with and through other HHS agencies.
Priority Target Area: Interoperability	Immediate Opportunities, Price Transparency	39	Cynthia Fisher	“Recommended HITAC Activity: Offer ideas for the role of health IT in improving price transparency of healthcare services.”	“ <b>Recommended HITAC Activity: Create a task force that will provide recommendations within 4 months, utilizing existing standards where possible and other technology tools, to efficiently implement real-time availability of price information in January 2021.</b> <del>Offer ideas for the role of health IT in improving price transparency of healthcare services.”</del> ”	No change was made. Rationale: This suggestion falls outside the scope of the HITAC processes; ONC would need to charge the HITAC to form such a task force. The existing text is broad enough to cover this circumstance.
Priority Target Area: Interoperability	Longer-Term Opportunities, Patient Matching	40 (also p.3)	Denise Webb	“Opportunity: Improve patient matching.”	Comment: “Recommend moving to immediate opportunities given the directive on patient matching given to ONC in the budget bill that was passed.”	Change was made. Rationale: Initial discussion by the HITAC on 1/15/20 showed interest in this adopting this suggestion, and the AR Workgroup concurs.
Priority Target Area: Interoperability	Longer-Term Opportunities, Standards for SDOH Data	40 (also p.3)	Denise Webb	“Opportunity: Develop and adopt standards for SDOH data collection, transfer, and integration for population health and individuals’ needs.”	Comment: “The timeframe for this doesn’t align with the timeframe for the activity related to SDOH under the privacy and security immediate opportunity related to SDOH on page 42. Suggest moving this to longer-term opportunities [tier] given all the other areas that need to be addressed and resolved first.” AR Workgroup modification: Move both SDOH opportunities to the Immediate Opportunity tier.	Change was made with modification. Rationale: Initial discussion by the HITAC on 1/15/20 showed interest in this addressing this suggestion.
Priority Target Area: Privacy and Security	Immediate Opportunities, Consent Information	41	Denise Webb	“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	Change was made. Rationale: AR Workgroup agrees that this change in word choice is fine.

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				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.”	agency <b>control</b> over how their data are exchanged.”  Comment: “Not sure if the use of “agency” here was intentional but seems like using “control” instead would be a better word choice.”	
Priority Target Area: Privacy and Security	Immediate Opportunities, Scope of Data Shared via FHIR	n/a (may be placed on p.42)	Ken Kawamoto		Insert: <b>“Opportunity: Increase capacity to reasonably restrict the scope of data via FHIR. There are approaches to placing reasonable restrictions to the scope of data shared via FHIR. For example, a filter could be placed between an EHR’s FHIR server and a third-party app so that the patient’s HIV and gonorrhea test results are not sent to a third-party app that does not need access to it.”</b> AR Workgroup modification: “Opportunity: Increase the capacity to reasonably restrict the scope of data shared via FHIR. There are approaches to placing reasonable restrictions <del>to</del> <b>on</b> the scope of data shared via FHIR. For example, a filter could be placed between an EHR’s FHIR server and a third-party app so that <del>the a</del> patient’s <del>HIV and gonorrhea</del> <b>highly sensitive</b> test results are not sent to a third-party app that does not need access to it.”	Change was made with modification to the proposed text. Rationale: AR Workgroup agrees that this opportunity should be addressed in this report.
Priority Target Area: Privacy and Security	Immediate Opportunities, Scope of Data Shared via FHIR	n/a (may be placed on p.42)	Ken Kawamoto		Insert: <b>“Recommended HITAC Activity: Convene a HITAC workgroup to review and provide recommendations on how federal agencies and standards development organizations could improve how reasonable restrictions</b>	Change was made with modification to the proposed text. Rationale: AR Workgroup agrees that this recommended HITAC activity

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					<p>are placed on the scope of data shared via FHIR. Potential actions may include 1) clarifying in ONC certification criteria that enabling such reasonable restrictions are allowed and encouraged and 2) updating underlying standards to support such reasonable restrictions in a standard manner.”</p> <p>AR Workgroup modification:                      “Recommended HITAC Activity: Convene a HITAC workgroup to review and provide <b>Review and make</b> recommendations on about how federal agencies and standards development organizations could improve how <b>the ability to place</b> reasonable restrictions are placed on the scope of data shared via FHIR <b>could be improved</b>. Potential actions may include Consideration could be given to 1) clarifying in ONC certification criteria that enabling such reasonable restrictions are <b>is</b> allowed, and 2) updating underlying standards to support such reasonable restrictions in a standard manner.”</p>	should be addressed in this report.
Priority Target Area: Interoperability	Longer-Term Opportunities, Exchange of SDOH	42 (also p.3)	Denise Webb	“Opportunity: Facilitate more exchange of SDOH data between healthcare providers and community service organizations and more patient education about consent.”	Comment: “See comment above on page 40 related to alignment of opportunity timeframe.”	TBD pending discussion by the Annual Report Workgroup Rationale: Initial discussion by the HITAC on 1/15/20 showed interest in this addressing this suggestion, and the AR Workgroup concurs.
Priority Target Area: Privacy and Security	Longer-Term Opportunities, Sharing Data across States	42	Cynthia Fisher	“Opportunity: Increase the alignment of data sharing policies across states.”	Move to Immediate Opportunities  “Opportunity: Increase the alignment of data sharing policies,	No change was made. Rationale: The legislative activity required for HITAC to be able to take action on this opportunity will not permit



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					including price information, across states”.	prioritization for the immediate term. Specific types of data are not called out elsewhere in the report, and will not be here for consistency.
Priority Target Area: Privacy and Security	Longer-Term Opportunities. De-Identified Data	42	Cynthia Fisher	“Opportunity: Increase awareness of technological capabilities to re-identify de-identified data.”	“Opportunity: Increase awareness of technological capabilities to re-identify de-identified data. Increase transparency and choice for patients with regard to the use of de-identified data.”	No change was made. Rationale: This text is nonspecific and redundant.
Priority Target Area: Patient Access to Information	Immediate Opportunities, Patient Portals	43	Cynthia Fisher	“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.”	“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 that provide clinical and financial (both price and payment) information would enable patients to become more engaged in their healthcare. Patients need to be able to share this information with innovative companies that can integrate the data and provide information from the data that is of high value to patients.”	No change was made. Rationale: The importance of price transparency to consumers is noted in other places in this report. Some of the suggested text is nonspecific and redundant.
Priority Target Area: Patient Access to Information	Immediate Opportunities, Patient Portals	43	Cynthia Fisher	“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.”	“Recommended HITAC Activity: Assess patient portals’ and patient-facing mobile apps’ operational effectiveness, patient engagement, and/or patient understanding and use of clinical and financial data to establish measures in the future.”	No change was made. Rationale: Specific types of data are not called out elsewhere in the report, and will not be here for consistency.
Priority Target Area: Patient Access to Information	Immediate Opportunities	n/a	Cynthia Fisher		Insert: “Opportunity: Improve real-time patient access to their health data and price information for items	No change was made. Rationale: These suggestions have been placed on the list of potential topics for

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		(would be p. 43)			<p>and services in the health care industry”</p> <p>“Patients lack real-time access to their health data and price information. This can cause a myriad of issues including inconsistent and uniform care decisions by patients and providers, patient safety concerns, and increased costs.”</p> <p>“Recommended HITAC Activity: Review and make recommendations regarding policies and future rulemaking that would allow innovators to use open APIs to aggregate health and price information and allow patients to access it in real-time.”</p> <p>“Recommended HITAC Activity: Determine mechanisms that hold actors (EHR vendors, networks, providers, and insurers) accountable for information blocking or withholding patient health information, inclusive of pricing and payment information. “</p> <p>“Recommended HITAC Activity: Identify critical data elements necessary for patients to understand the price of health care items and services prior to delivery. Help ONC determine and define policy needs and functional requirements for patient access to a pre-adjudication, authorization, explanation of benefits, combined with pricing and coverage, before receiving care.”</p>	consideration for the FY20 annual report.
Priority Target Area: Patient	Immediate Opportunities	n/a	Cynthia Fisher		Insert: “Opportunity: Improve real-time transparency into patient clinical data and price and payment	No change was made. Rationale: These suggestions have been placed on the list





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Access to Information		(would be p. 43)			<p>information in health care IT products.”</p> <p>“Price data and clinical information is not easily connected in health IT systems and therefore it is nearly impossible to get a clear and accurate picture of how the data interacts, both in real-time and when determining trends.”</p> <p>“Recommended HITAC Activity: Develop a workgroup to identify current inefficiencies that increase costs of care and recommend best practices and regulatory opportunities to improve price transparency.”</p> <p>“Recommended HITAC Activity: Suggest recommendations for standards that would connect price and clinical information data such that innovative technology companies and app developers can readily provide the consumers with a functional nationwide marketplace for healthcare. Recommended HITAC Activity: Suggest recommendations to link prices to clinical experience and payment information, to provide a timely, comprehensive bill, with digital provenance of payment and payment method.”</p>	of potential topics for consideration for the FY20 annual report.
Priority Target Area: Patient Access to Information	Immediate Opportunities, Patient Engagement Roadmap	43	Cynthia Fisher	<p>“Opportunity: Develop an updated roadmap for patient engagement and access to data that is less dependent on providers and their EHR developers.</p> <p>Patients continue to experience challenges in accessing and</p>	<p>“Opportunity: Develop an updated roadmap for patient engagement and access to data that is less dependent on providers and their EHR developers.</p> <p>Patients continue to experience challenges in accessing and aggregating their data from</p>	No change was made. Rationale: The suggested statement lacks documentation, and therefore does not add value to the existing text.

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				aggregating their data from providers and EHR developers.”	providers and EHR developers. <b>Structural barriers in the current system are preventing innovative solutions from being built to improve the patient experience.”</b>	
Priority Target Area: Patient Access to Information			Andrew Truscott		Comment: The number of recommended activities for this priority target area is disproportionate compared to the other Priority Target Areas. Recommend adding a recommendation around Price Transparency.	No change was made. Rationale: The AR Workgroup believes that the number of activities for a priority target area may not indicate its importance, urgency, or complexity. The topics chosen for inclusion in the report reflect the current needs across the industry, including the patient/caregiver stakeholder group. There may be many topics and activities chosen for a priority target area one year, and only a few in another year.
<b>Conclusion</b>						
Conclusion		44	AR Workgroup	<p>FY18 report:                      In FY19, ONC and the HITAC will continue to focus on advancing the implementation of the health IT provisions of the Cures Act including information blocking, certification enhancements, and the Trusted Exchange Framework and Common Agreement, as well as address emerging issues.</p> <p>FY19 draft report, 1/15/20:                      In FY20, ONC and the HITAC will continue to ...[Note: More text will be inserted after final HITAC 2020 Plan publication.]</p>	In FY20, ONC and the HITAC will continue to focus on advancing the implementation of the health IT provisions of the Cures Act including the EHR Reporting Program and the Trusted Exchange Framework and Common Agreement, as well as address emerging issues including the intersection of clinical and administrative data standards.	Change was made.

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<b>Other</b>						
General Structure			Denise Webb		Comment: "Recommend once the report is finalized that numbering be added to the sections and subsections, particularly for the immediate and longer-term opportunities and related recommendations on pages 39-44."	No change was made. Rationale: This approach might be useful for the recommendations section to help with future recommendations tracking tasks. However, numbering within the sections might imply a sequence or ranking of the topics that doesn't exist. The table of contents, footers, and heading styles already show the organization of the report sufficiently.
General Structure			Denise Webb		Comment: "Recommend adding an appendix that has a traceability matrix with the X axis across the top having the various titled outputs of the committee TFs/Workgroups with hyperlinks and the Y axis with the numbered opportunity areas and each recommended activity. Place a checkmark in each cell where there is linkage between the opportunity activity recommendation to specific previous work/recommendations of the committee and where in the work product the information can be found, such as page number. This will make it easier to maintain traceability and tracking and hopefully prevent rehashing topics."	No change was made. Rationale: The HITAC's transmitted recommendations and the recommended activities in this report differ in nature, e.g., purpose and level of detail, so this linkage does not exist. However, these suggestions have been placed on the list of potential topics for consideration for the FY20 annual report.
General Structure			Leslie Lenert		Provide traceability from the recommendations in the report to their source from HITAC-approved recommendations generated from the task forces.	No change was made. Rationale: Please see prior comment.
Terminology		18	ONC		As of 1/17/20, ONC prefers to use the term "clinician" rather than	No change was made.



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					<p>“provider” in public-facing materials. If ONC uses “provider,” the word “healthcare” should precede it. Therefore, this change was made for the Clinician Burden Reduction bullet in the FY19 annual report for increased accuracy about that specific federal initiative. What is the HITAC’s preference generally? Does the HITAC want to make the switch for the other 166 instances in the FY19 annual report, or wait until the next annual report cycle to address this preference as well?</p>	<p>Rationale: Keep existing “provider” language. Can consider concern again for FY20 annual report.</p>