

# Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT



## Consumer Workgroup

### Interoperability Roadmap Comments

Christine Bechtel, chair

April 7, 2015

# Consumer Workgroup Members



Health IT Policy Committee  
A Public Advisory Body on Health Information Technology  
to the National Coordinator for Health IT

- **Christine Bechtel**, Bechtel Health Advisory Group (Chair)
- **Dana Alexander**, Caradigm
- **Leslie Kelly Hall**, Healthwise
- **Ivor Horn**, Seattle Children's
- **Erin Mackay**, National Partnership for Women & Families
- **Philip Marshall**, Conversa Health
- **Amy Berman/Wally Patarawan**, The John A. Hartford Foundation
- **Will Rice**, Walgreens/Take Care Health Systems
- **Clarke Ross**, Consortium for Citizens with Disabilities; American Association on Health and Disability
- **Luis Belen**, National Health IT Collaborative for the Underserved

- **Kim Schofield**, Lupus Foundation of America (GA Chapter) Work@Health Program for CDC
- **MaryAnne Sterling**, Patient & Caregiver Advocate
- **Nicholas Terry**, Indiana University, Robert H. McKinney School of Law

## Ex Officio Members

- **Cynthia Baur**, HHS, CDC
- **Teresa Zayas Caban**, HHS, AHRQ
- **Danielle Tarino**, HHS, SAMHSA
- **Theresa Hancock**, Veterans Affairs
- **Bradford Hesse**, HHS, NIH
- **Wendy J. Nilsen**, HHS, NIH

## ONC Staff

- **Chitra Mohla**, Office of Policy (Lead WG Staff)



1. Workgroup Charge and Context
2. Overarching Comments
3. Section C Comments
4. Section D Comments



# WORKGROUP CHARGE AND CONTEXT



Provide input and make recommendations on policy issues or opportunities to use health IT to:

- Engage consumers and families in their own health and health care
- Enable consumer-provider partnerships supported by health IT
- Elevate consumer voices to shape health system transformation



# Overarching Comments



- Partnership between clinicians, patients and family caregivers should be an essential building block in the Learning Health System (LHS); Building block B already states “a supportive business and regulatory environment that encourages interoperability.”

## Rules of engagement and governance

A. Shared governance of policy and standards that enable interoperability

## Supportive business, clinical, cultural, and regulatory environments

B. A supportive business and regulatory environment that encourages interoperability

C. Individuals are empowered to be active managers of their health

D. Care providers partner with individuals to deliver high value care

## Privacy and security protections for health information

## Certification to support adoption and optimization of health IT products and services

I. Stakeholder assurance that health IT is interoperable

## Core technical standards and functions

J. Consistent data formats and semantics; K. Consistent, secure transport technique(s);

L. Standard, secure services; M. Accurate identity matching; N. Reliable resource location



- Consider merging Section C & D to support the partnership and streamlining the overall effort of achieving a LHS
- Rapidly changing role of the Consumer and evolution of technology is not well reflected in the overall plan. EHRs appear to be the central focus
- *Global comment:* Replace “others” with “Authorized family members and other authorized caregivers” throughout the roadmap.
- *Global comment:* Replace “care plan” with “person centered plan” because healthcare is a piece of the plan but includes other areas such as community services and long term care services.
- A realistic vision of what interoperability will/should look like in 2024. If truly patient-centric model, the patient will be the dominant curator of health information.





# **Specific Comments on Section C**

# Section C: Cultural change for individuals including demanding and using their electronic health information

Item	Comments
<b>C1. Cultural change for individuals including demanding and using their electronic health information</b>	<p><b>1. <u>Call to action</u>: A majority of individuals and their caregivers should demand access to their electronic health information in a format they can use to manage their health or that of others.</b></p> <p>Roadmap strongly supports empowering and engaging consumers but the term “demand” is not conducive to fostering a partnership between consumer and provider</p> <ul style="list-style-type: none"><li>• Consumers should not have to demand access to their information – right guaranteed under HIPAA.</li><li>• Suggest replacing <u>demand</u> with <u>will</u></li></ul> <p><b>3. <u>Call to action</u>: Individuals should contribute clinically relevant patient-generated health data and request corrections to their electronic health information to effectively manage their interactions with the care delivery system and to manage their health and wellness where they live, work and play</b></p> <p>Consumers need easy, obvious ways to contribute data, as well as to flag inaccurate data using health IT tools.</p> <ul style="list-style-type: none"><li>• Amendments/corrections, etc. should be better developed and deployed in the shorter term</li><li>• Systems should be flexible meeting differences in capacity</li><li>• Important advances needed around language access, including offering health information in the top 5 languages nationally</li></ul>

## Section C:

### Cultural change for individuals including demanding and using their electronic health information

Item	Comments
C1. Cultural change for individuals including demanding and using their electronic health information	<p data-bbox="266 315 1881 458"><b><i>4. Call to action: Individuals and their extended care teams (including family and caregivers) should utilize care planning to capture individual goals and preferences as part of longitudinal health information used across care settings.</i></b></p> <ul data-bbox="266 511 1881 1315" style="list-style-type: none"><li data-bbox="266 511 1881 739">• Accelerate this call to action to support new models of care that are already underway<ul data-bbox="459 639 1881 739" style="list-style-type: none"><li data-bbox="459 639 1881 739">○ Develop functionality along a broader consensus on the attributes of an ideal planning process</li></ul></li> <li data-bbox="266 811 1881 1315">• Person Centered Planning should include (potential data gaps currently):<ul data-bbox="363 939 1881 1315" style="list-style-type: none"><li data-bbox="363 939 1881 982">• Goals for Care</li><li data-bbox="363 996 1881 1039">• Direction</li><li data-bbox="363 1053 1881 1096">• Advance directives</li><li data-bbox="363 1110 1881 1153">• Values base direction such as religious preferences</li><li data-bbox="363 1168 1881 1210">• Care giver/support team</li><li data-bbox="363 1225 1881 1268">• HHS/IOM Standards for Race/Ethnicity, Language</li><li data-bbox="363 1282 1881 1315">• Social Determinants of Health</li></ul></li></ul>

## Cultural change for individuals including demanding and using their electronic health information

Item	Comments
<p>C2. Providers and technology developers supporting individual empowerment</p>	<p><b>1. <i>Call to Action: ONC, government and the industry will identify best practices for the incorporation of patient-generated health data in health care delivery.</i></b></p> <ul style="list-style-type: none"> <li>• WG supports PGHD - need to focus on implementing already known best practices “on the ground”, identifying new ones, beyond those that have already been developed through white papers and the FACA work.</li> <li>• Rapidly growing market for devices and wearables a source of PGHD, standards need to be developed and/or agreed to as well as implemented by 2018.</li> </ul> <p><b>5. <i>ONC and government ensure that patients understand their ability to access, send and receive health information.</i></b></p> <ul style="list-style-type: none"> <li>• This should be more comprehensive and focused on digital health literacy: include patient and family education and engagement around understanding the value, and privacy implications of health IT and the “how to”</li> <li>• Develop tool kits for providers as part of a larger digital literacy initiative, as well as consideration of vulnerable and diverse populations who may require different outreach strategies.</li> </ul>

# Section C: Cultural change for individuals including demanding and using their electronic health information

Item	Comments
<p>C2. Providers and technology developers supporting individual empowerment</p>	<p><b>6. <u>Call to action:</u> Providers and technology developers should support the incorporation of patient-generated health data in health care delivery, which may include advance directives, remote monitoring, glucose levels and other data individuals are tracking</b>  <i>2018-2020: Expand interoperable health IT and users</i></p> <ul style="list-style-type: none"> <li>• Essential in this time frame that providers can easily receive, upload, understand and act upon patient-sourced data in usable and safe ways</li> <li>• Consider a <u>new call to action</u>: 2015-2017 for vendors to collaborate with providers in developing capacity</li> </ul> <p><b>7. <u>Call to action:</u> Technology developers should deploy innovative aggregation platforms and tools that allow individuals and caregivers to receive and compile health information from multiple sources in one place, send their data to a destination of their choice and find and use the information they need (as determined by the individual), to support for example, the individual participating in shared decision-making with their care team.</b></p> <ul style="list-style-type: none"> <li>• Implement sooner than 2018-2020 for the uptake of Blue Button and VDT, as required in MU2</li> <li>• Aggregation platforms will alleviate portal proliferation and portal fatigue</li> <li>• Should include link to patient education materials</li> </ul> <p><b>8. <u>Call to action:</u> Providers should welcome and use information from other providers to avoid duplication of tests and ensure coordinated care.</b></p> <ul style="list-style-type: none"> <li>• Providers should not just welcome data from other providers but from consumers and family caregivers as well.</li> </ul>

## Section C:

### Cultural change for individuals including demanding and using their electronic health information

Item	Comments
C3. Privacy and Security for Individuals	<p>1. <b><i>Call to action: Public and private sector stakeholders should <u>assess</u> whether people understand how to safeguard their health information and the need for resources related to this topic.</i></b></p> <p>Call to action should go beyond assess and leverage knowledge about consumer awareness and privacy that is already known</p> <ul style="list-style-type: none"><li>• HIPAA notices are not adequate – policy gaps exist with respect to mobile apps and other technologies</li><li>• Need to educate consumers on safeguarding information in a new and rapidly evolving environment</li></ul> <p>2. <b><i>Call to action: Providers should provide individuals with secure access to their own behavioral health information in a manner that is easy to use and enables them to make choices about disclosure of specific information that is sensitive to the individual and/or legally protected.</i></b></p> <ul style="list-style-type: none"><li>• Segmentation of data should include ANY data that patient feels is sensitive not just behavioral health</li></ul>

## Section C:

### Cultural change for individuals including demanding and using their electronic health information

Item	Comments
C4. Education and digital health literacy for individuals	<p><b><i>1. Call to action: Consumer advocacy groups in collaboration with government agencies, associations and payers should develop and disseminate resources (toolkits and best practices) based on consumer needs to assist individuals with increasing their digital health literacy. This supports consumer participation in shared decision making with their care team based on more complete and accurate information</i></b></p> <ul style="list-style-type: none"><li>• Health literacy and digital literacy are national problems should be addressed on a national scale by Federal government in partnership with consumer advocacy groups. Federal government must develop comprehensive strategy, tools and resources for all stakeholders.</li></ul> <p><b><i>4. Call to action: ONC and the industry should work with individuals to ensure that a majority understand the value of sustained engagement in managing their health, supported by health IT.</i></b></p> <ul style="list-style-type: none"><li>• Should be part of an overall communication strategy to help individual understand privacy and security and the value of health IT</li><li>• Ongoing “patient engagement” initiatives, and the Interoperability Roadmap should focus on enabling the technology to support consumer, family caregiver and provider partnerships in the achievement of shared health and care goals</li></ul>



# **Specific Comments on Section D**



## Section D: Care Providers Partner with Individuals to Deliver High Value Care

### General Comments

- Section D should be revised to better emphasize the clinical-patient –family partnership.
- Section is very provider focused, even in sections where consumers and families have an important role to play (example: Governance)
- Section D is potentially overwhelming; providers report being overwhelmed with requirement today (MU, PQRS, ICD 10, etc.)

Overall we suggest:

- Focus more on outcomes and less on process.
- Combining this with Section C could also help

## Section D: Care Providers Partner with Individuals to Deliver High Value Care

Category	Comments
<b>D2. Providers embrace a Culture of Interoperability and work with vendors and other supporting entities to improve interoperability</b>	<p><b>1. Call to action: Providers should routinely expect electronic access to outside information in the provision of care and engage with other providers to send, receive, find and use health information for their patients.</b></p> <ul style="list-style-type: none"><li>• <u>New call to action:</u> Vendors should build tools and interfaces that make all relevant information, including information from patients and other providers, easy to digest and act upon for providers, so it becomes a seamless part of their workflow.</li><li>• Develop tools that make data actionable for providers</li></ul> <p><b>2. Call to action: Providers should recognize that valuable clinical information about their patients may reside with patients or caregivers themselves and that they may need to incorporate that information into their decision making.</b></p> <ul style="list-style-type: none"><li>• Strongly support this concept. However, must be focused on enabling providers to efficiently use data – not just encouraging them to “value it.”</li><li>• If data is valuable and easy to use providers will use the data</li></ul>

## Section D: Care Providers Partner with Individuals to Deliver High Value Care

Category	Comments
D2. Providers embrace a Culture of Interoperability and work with vendors and other supporting entities to improve interoperability, continued	<p data-bbox="305 301 1875 425"><b><i>4. Call to action: Providers and their organizations should ensure contracts and agreements that they sign and re-sign with technology developers include necessary requirements for interoperability, to ensure they can share and incorporate patient information</i></b></p> <p data-bbox="305 482 1895 639">Need to remove barriers to ensuring sharing and incorporation of patient information such as excessive fees charged by vendors for building interfaces and additional fees for data to flow through the interfaces</p> <p data-bbox="305 711 1837 835"><b><i>8. Call to action: Providers and their organizations should work with necessary parties to configure systems so that the presentation of information to providers is configurable based on use case, provider specialty and other characteristics, to facilitate usability and patient safety.</i></b></p> <p data-bbox="305 892 1818 1049">Priority use case: Bi-directional, dynamic person-centered planning oriented around share health and care goals supporting care coordination, person and family engagement and interoperability</p>

## Section D: Care Providers Partner with Individuals to Deliver High Value Care

Category	Comments
<b>D2. Providers embrace a Culture of Interoperability and work with vendors and other supporting entities to improve interoperability, continued</b>	<p><b><i>10. Call to action: Providers should routinely use and have access to robust and clinically relevant decision support (e.g. for medication management).</i></b></p> <p>Progress should be made towards integrating shared decision making tools with clinical decision support</p> <p><b><i>12. Call to action: Providers should receive and provide continuous feedback to support the improvement of decision-making, care processes and outcomes. ( 2021 -2024)</i></b></p> <p>If providers have started doing this in the previous time period, and quality measures and payment are aligned, this will be the natural outcome and may not require a separate call to action.</p>

# Section D: Care Providers Partner with Individuals to Deliver High Value Care

Category	Comments
<p><b>D 3. Accurate Measurement</b></p>	<ol style="list-style-type: none"> <li><b>1. Call to action: Providers should leverage data beyond their internal systems for population health analytics and quality measurement</b></li> <li><b>2. Call to action: Providers and other stakeholders should use standard metrics of interoperability to monitor and track improvement.</b></li> <li><b>5. Call to action: Public and private stakeholders should objectively measure and value interoperability and information sharing as an indicator of care coordination, quality and efficiency.</b></li> </ol> <p>WG supports these essential calls to action. Suggest the following:</p> <ul style="list-style-type: none"> <li>• Government should invest in development of more advanced eCQMs. Include harmonizing quality, population health, MU common data set, consumer information technology(2015-2017)</li> <li>• Focus on the purpose of interoperability – develop measures for care-coordination, communication and health outcomes instead of measuring interoperability (2018-2020)</li> <li>• Payment for outcomes that require interoperability – like robust care coordination, person-centered planning, eVisits, reduction in duplicative testing etc.</li> <li>• Government must outline a strategy for revision of current measure sets, new payment approaches to incentive performance</li> </ul>
<p><b>D 4. Interoperability of processes and workflow</b></p>	<p>Suggest re-evaluating this section entirely. Focus on managing workflows may not be needed if, per the previous section, progress has been made in advancing measurement and payment.</p>

## Section D: Care Providers Partner with Individuals to Deliver High Value Care

Category	Comments
D 5: Training and maintenance of certification for providers	Workgroup is not commenting on this section
D 6. Innovation and Generation of New Knowledge and Evidence	<p data-bbox="305 536 1899 665"><b><i>1.Call to action: Providers currently engaged in clinical research and quality improvement should work together with research institutions and other public and private stakeholders to establish a strategic plan for research and the generation of new knowledge.</i></b></p> <p data-bbox="305 718 1528 758">This call to action should include patients, families and their advocates</p> <p data-bbox="305 819 707 859"><b><u>Overarching Comment</u></b></p> <p data-bbox="305 921 1885 1079">Given the large amount of federal funds dedicated to research, and the importance of federal funds and policy in promoting innovation, there should be a clearer role articulated for government.</p>

## Section D: Care Providers Partner with Individuals to Deliver High Value Care

Category	Comments
D 7. Transparency of Value and engagement of patients families and caregivers	<p><b>1. Call to action: Providers should work together with purchasers of care to have access to patient out-of-pocket costs and those of payers and purchasers. Providers are engaged in regional efforts to measure quality and maximize value.</b></p> <p>Patients, families and their advocates should also be engaged in regional efforts to measure quality and maximize value.</p> <p><b>4. Call to action: Providers should routinely utilize cost and quality data to make shared diagnostic and treatment planning decisions.</b></p> <ul style="list-style-type: none"><li>• Clarify- Shared decision <u>with</u> patients and families.</li><li>• Consumers must be at the table to design the process, particularly where cost and quality data are involved. Cost focus can be risky if done without consumer involvement.</li></ul> <p><b>5. Call to action: Providers should work together with purchasers of care to develop, test and implement appropriate and credible indicators of value.</b></p> <ul style="list-style-type: none"><li>• Harmonize with Section D3 (earlier section on quality and measurement)</li><li>• Federal investment needed to create credible, meaningful measures of value</li></ul>

## Section D: Care Providers Partner with Individuals to Deliver High Value Care

Category	Comments
D 7. Transparency of Value and engagement of patients families and caregivers	<p><b>6. Call to action: Providers should support consumer-facing services such as:</b></p> <ul style="list-style-type: none"><li><i>o Online scheduling</i></li><li><i>o Medication refill requests</i></li><li><i>o Electronic/Telehealth Visits</i></li><li><i>o Patient provided device data, screenings and assessments</i></li><li><i>o Informed consent and education modules</i></li><li><i>o Integration of patient generated health data in the medical record</i></li><li><i>o Patient-defined goals of care</i></li><li><i>o Shared care planning</i></li></ul> <ul style="list-style-type: none"><li>• Timeline should be earlier than 2018-2020; especially for those included in MU2</li><li>• eVisits, telehealth and devices needed much more work and can be separated compared to the other areas</li><li>• Recommend this amended call to action be integrated with Section C</li></ul> <p><b>8. Call to action: Providers and individuals should work together to substantially reduce the burden of care coordination through patient-centered tools and sharing and use of electronic health information.</b></p> <p>A measure of the outcome would be more appropriate here – that care is actually more coordinated, high-value, and patient- and family-centered.</p>





# Questions

## Consumer Workgroup Comments on Interoperability Roadmap

The Consumer Work Group of the HIT Policy Committee is pleased to submit comments on *Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap*.

We were asked to consider Sections C & D, and have done so from the viewpoint of both consumers<sup>1</sup> and the other stakeholders we collectively represent.

As an overall matter, we believe that “supportive business, clinical, cultural and regulatory environments” does not adequately reflect the building block it is intended to. It is far more important to focus on partnership between clinicians, patients and family caregivers as an essential building block, particularly since B) within this building block already states “a supportive business and regulatory environment that encourages interoperability.” The clinical and cultural elements stem from the partnership between patients, providers and family caregivers. It is this partnership that is most important to highlight, while preserving the calls to action that help create supportive business, clinical, cultural and regulatory environments.

Further, as we called for in our comments on the Federal Strategic Plan, we believe that more must be done to strengthen and reinforce partnership between patients, family caregivers and clinicians by aligning around shared goals for health and care. To that end, we strongly encourage ONC to consider merging Section C and Section D. While there are many actions that providers and consumers can take independently, there are many more actions that can be taken together. By combining the sections, much streamlining can also be accomplished, reducing overall effort of achieving the important goal of a Learning Health System.

At a minimum, Section D needs far more emphasis on joint consumer-clinician action than it currently reflects.

We also comment that the role of the consumer is changing rapidly. Whereas two years ago, patient-generated health data was one of the “newest constructs,” today we are coming to see the potential for many consumers to become curators or stewards of their own health information, and for that curated information to be potentially far more complete than that which is contained in any single provider’s EHR. The rapid evolution of technology and the consumer role is not well reflected overall in the plan. It seems to be heavily EHR-influenced.

Finally, a word about language. Throughout the plan we suggest:

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<sup>1</sup> Throughout our comments we use the terms, “patient,” “person,” “consumer,” etc. There is no widely-agreed upon approach to terminology today, and we agree with the National Quality Forum that “one single term cannot apply to all individuals in all situations; in actuality, an individual with many needs may self-identify as a person, client, or patient at a single point in time.” Generally speaking, we are referring in all cases to people who receive and manage their health care

## Consumer Workgroup Comments on Interoperability Roadmap, continued

- There are several references to “care plans” and the “care team.”
  - Replace “care plan” with “person centered plan” because health care is a piece of the plan but includes other areas such as community services and long term services and supports.
  - Replace care team as appropriate with “care, supports and services team”
  - Be thoughtful about the use of the word “others.” There are several places in the plan where “others” is used to describe authorized family caregivers, but that should be clearer.

### Specific Comments

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#### Section C: Individuals are Empowered Active Partners in Their Health and Health Care

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#### C1. Cultural change for individuals including demanding and using their electronic health information

##### 2015-2017: Send, receive, find and use a common clinical data set

1. ***Call to action: A majority of individuals and their caregivers should demand access to their electronic health information in a format they can use to manage their health or that of others.***
  - The roadmap strongly supports empowering and engaging consumers but the term “demand” is not conducive to fostering a partnership between the consumer and provider. In addition, consumers should not have to demand access to their information since that right is guaranteed under HIPAA. We suggest replacing the term demand with will.
  - ONC should instead focus on facilitating and enhancing individuals’ ACTIVE USE of online access, VDT, BlueButton, and other methods of health information access and use.
  - ***New call to action:*** Institutional purchasers and vendors should include individuals and caregivers in the co-creation of digital health information tools that can securely exchange health information. Having tools that are well designed for consumers will go far in advancing both access to and use of health information.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### 2018-2020: Expand interoperable health IT and users

2. ***Call to action: An increasing proportion of individuals and caregivers should demand and ask for access to their electronic health information in a format they can use to manage their health or that of others.***

- We repeat the comment above about the word “demand.”

### 2018-2020:Expand interoperable health IT and users

3. ***Call to action: Individuals should contribute clinically relevant patient-generated health data and request corrections to their electronic health information to effectively manage their interactions with the care delivery system and to manage their health and wellness where they live, work and play***

- Managing health data, including making both contributions and corrections, is an essential component of the kind of empowerment the Roadmap seeks to foster. We strongly agree that consumers need easy, obvious ways to contribute data, as well as to flag inaccurate data using health IT tools. However, making amendments/corrections, etc. should be better developed and deployed in the shorter term, as opposed to 2018, since federal policy is already spurring the implementation of VDT and Blue Button.
- In addition, the features and design of technology that enables consumers to better manage their data and their health care interactions will be a significant role achieving this call to action. Overall, those technologies and features must be designed to accommodate diverse consumer needs. Understanding differences in capacity – including some individuals who may want to be curators of their data or co-curate in partnership with the provider, and other patients may not want or have the ability to manage their own data, is essential. Effective management will also include making important advances around language access, including offering health information in the top 5 languages nationally.
- Designated family or other caregivers should be included in this call to action.

4. ***Call to action: Individuals and their extended care teams (including family and caregivers) should utilize care planning to capture individual goals and preferences as part of longitudinal health information used across care settings.***

- The workgroup proposes replacing “Care Planning” with “Person Centered Planning,” as noted above.
- This call to action should be accelerated to support new models of care that are already underway. Developing this functionality along with a broader consensus on the attributes of an ideal planning process and the concomitant enabling technology is critical in earlier phases of the roadmap.
- Person Centered Planning should include (potential data gaps currently):
  - o Goals for Care
  - o Direction

## Consumer Workgroup Comments on Interoperability Roadmap, continued

- Advance directives
- Values base direction such as religious preferences
- Care giver/support team
- HHS/IOM Standards for Race/Ethnicity, Language
- Social Determinants of Health

5. ***Call to action: Individuals should regularly access and contribute to their health information in health IT, send and receive electronic health information through a variety of emerging technologies and use the information to manage and participate in shared decision making with their care team.***

### **C2. Providers and technology developers supporting individual empowerment**

#### **2015-2017: Send, receive, find and use a common clinical data set**

1. ***Call to action: ONC, government and the industry will identify best practices for the incorporation of patient-generated health data in health care delivery.***
- The workgroup supports PGHD but there is a need to focus on implementing already known best practices “on the ground”, and identifying new ones, beyond those that have already been developed through white papers and the FACA work.
  - PGHD is included in MU3. In order for this information to be valuable vendors need to build functionality so the data is usable and useful for providers and patients.
  - The rapidly growing market for devices and wearables will be a source of PGHD, standards need to be developed and/or agreed to as well as implemented by 2018.
2. ***Call to action: Providers should encourage their patients to access their health information online and will enable patients to view, download and transmit that information to a destination of the patient’s choice.***
- We agree that providers need to participate in the education process so that consumers are comfortable using these tools and accessing their health information. They are natural and highly trusted messengers. As we comment below, providers will need tools and resource for this work.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

3. ***Call to action: Providers and technology developers should provide a majority of individuals with the ability to send and receive their health information and make decisions with the providers of their choice, including but not limited to their existing care team based on their preferences.***
  - Technologies like "Set and Forget" will make it easier and more appealing for patients and family caregivers to receive and manage their health information. Enabling patients and families to register the destination app of their choice so that all changes occurring automatically sent to the app should be considered as another call to action in this section. And again, developers should include consumers in the design and usability of these tools.
4. ***Call to Action: ONC will work with the technology community to increase the use of Blue Button through implementation of a portfolio of standards to support consistency in the way that individuals receive information.***
5. ***Call to Action: ONC and government ensure that patients understand their ability to access, send and receive health information.***
  - This is the first of several calls to action that involve patient and family education and engagement around understanding the value, and privacy implications of health IT. These actions should not live in separate categories – they should be combined and streamlined together. A recent national survey<sup>2</sup> of consumers on health IT shows an important link between value and privacy – and suggests that consumers need to hear about both issues together. These two issues also cannot be divorced from digital health IT literacy – how consumers and families can use health IT to better manage their health and care.
  - It would not be responsible to ensure people understand their ability to access, send and receive health information without talking about privacy and security policy issues and best practices. The workgroup strongly suggests bringing all related education and engagement items together in a more streamlined fashion to reflect engagement around value, privacy and "how-to."
  - This will of course necessitate development of tool kits for providers as part of a larger digital literacy initiative, as well as consideration of vulnerable and diverse populations who may require different outreach strategies.

### **2018-2020: Expand interoperable health IT and users**

6. ***Call to action: Providers and technology developers should support the incorporation of patient-generated health data in health care delivery, which may include advance directives, remote monitoring, glucose levels and other data individuals are tracking***

It is essential in this time frame to have created ways that providers can easily receive, upload, understand and act upon patient-sourced data in usable, safe ways. ONC should consider a new call to action in 2015-2017 for vendors to collaborate with providers in developing capacity.

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<sup>2</sup> National Partnership for Women & Families, 2014.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

7. ***Call to action: Technology developers should deploy innovative aggregation platforms and tools that allow individuals and caregivers to receive and compile health information from multiple sources in one place, send their data to a destination of their choice and find and use the information they need (as determined by the individual), to support for example, the individual participating in shared decision-making with their care team.***

- This is an important call to action and needs to be implemented sooner than the 2018 -2020 time frame if individuals and caregivers are to utilize Blue Button and VDT, as MU2 calls for. Aggregation platforms will also alleviate portal proliferation and portal fatigue, which is already beginning to occur in the market.

8. ***Call to action: Providers should welcome and use information from other providers to avoid duplication of tests and ensure coordinated care.***

- This is an important element for interoperability and should happen before 2018. It will require provenance, “tamper proof seal,” equal level of assurance for all stakeholders to include transparent directories for public level secure email exchange.
- In addition, providers should not just welcome data from other providers but from consumers and family caregivers as well.

### **2021-2024: Achieve a nationwide LHS**

9. ***Call to action: Providers and health IT developers should provide a majority of individuals/caregivers the ability to contribute as needed to their electronic health information and support the incorporation of patient-generated health data.***

This call to action should be implemented in an earlier timeframe. At this point (2021 – 2024), stakeholders should be at best refining this process and the tools, and offering all individuals and family caregivers this ability.

### **C3. Privacy and Security for Individuals**

#### **2015-2017: Send, receive, find and use a common clinical data set**

1. ***Call to action: Public and private sector stakeholders should assess whether people understand how to safeguard their health information and the need for resources related to this topic.***

## Consumer Workgroup Comments on Interoperability Roadmap, continued

- Much is already known about consumer awareness and privacy, and this call to action should leverage that knowledge and be far more advanced than an assessment. We know that HIPAA notices are not adequate, and that we have policy gaps with respect to mobile apps and other technologies not covered under HIPAA. We must begin to help consumers understand how to safeguard their information in a new and rapidly evolving environment.

2. ***Call to action: Providers should provide individuals with secure access to their own behavioral health information in a manner that is easy to use and enables them to make choices about disclosure of specific information that is sensitive to the individual and/or legally protected.***

Segmentation of data should include ANY data that patient feels is sensitive not just behavioral health. It is important to include the behavioral health community (and other providers not eligible for Meaningful Use), in policy and implementation discussions.

### **2018-2020 Expand interoperable health IT and users**

3. ***Call to action: Individuals should be able to trust that their health information (such as that generated/collected via home monitoring devices or other emerging technologies) is protected and secure.***

While we agree with this goal, this is an immediate need. If we wait until 2018, it may undermine consumer/patient trust. We urge ONC to consider immediate work in the area of policy gaps and consumer education with respect to privacy and security in today's environment, particularly as VDT begins to gain more traction and use in the marketplace.

### **2021-2024 Achieve nationwide LHS**

4. ***Call to Action: ONC and the industry will continue to provide individuals with relevant and updated resources based on current technology to assist with increasing their digital health literacy.***

As noted above, we support implementation of an earlier initiative to boost digital health literacy, value and understanding of privacy and security. That will set the stage for this call to action to continue. We support the notion that as technology evolves, education and engagement must evolve with it. Consumers, advocates and family caregivers should be included in the creation of tools and resources to ensure that the tools adapt to digital health literacy differences.



## Consumer Workgroup Comments on Interoperability Roadmap, continued

### C4. Education and digital health literacy for individuals

#### 2015-2017: Send, receive, find and use a common clinical data set

1. ***Call to action: Consumer advocacy groups in collaboration with government agencies, associations and payers should develop and disseminate resources (toolkits and best practices) based on consumer needs to assist individuals with increasing their digital health literacy. This supports consumer participation in shared decision making with their care team based on more complete and accurate information***

- While we understand and support the essential role for consumer groups in this process, the workgroup is concerned health literacy and digital literacy are national problems that need to be addressed on a national scale. Consumer Advocacy groups likely do not have the budgets to develop and implement the level of education needed to improve health literacy in the country. They can serve as partners but the federal government must develop a comprehensive strategy, tools and resources for all stakeholders – providers, consumers, vendors, and others.

#### 2018-2020: Expand interoperable health IT and users to improve health and lower cost

- ***Call to Action: ONC, government and the industry should work with individuals to help the majority understand the value of health IT for managing their health by providing individuals with easy resources to assist with increasing their digital health literacy.***
- As noted above, value cannot live in a separate category from privacy, security and the skills to use consumer-facing health IT. It would not be responsible to ensure people understand the value of health IT without talking about privacy and security policy issues and best practices. The workgroup strongly suggests bringing all related education and engagement items together in a more streamlined fashion to reflect engagement around value, privacy and “how-to.” These activities to enhance individuals’ understanding and engagement should be taking place now (rather than the next six to ten years), if we are to move towards a Learning Health System by 2024. The resources should include the risks and benefits of health IT for managing and exchanging health information. Resources and tools should adapt to digital health literacy differences.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

2. ***Call to Action: ONC and the industry should continue to provide individuals with relevant and updated resources based on current technology to assist with increasing their digital health literacy.***

- The Workgroup suggest combining #1 and # 2 calls to action.

### **2021-2024: Achieve nationwide LHS**

3. ***Call to action: ONC and the industry should work with individuals to ensure that a majority understand the value of sustained engagement in managing their health, supported by health IT.***

- Again, this call to action should be part of an overall communication strategy to help individuals understand the privacy, security and value of health IT in a learning health system. There are many “patient engagement” initiatives underway, and the Interoperability Roadmap should focus on enabling the technology to support consumer, family caregiver and provider partnerships in the achievement of shared health and care goals.

4. ***Call to action: ONC and the industry should continue to provide individuals with relevant and updated resources based on current technology to assist with increasing their digital health literacy.***

Rephrase: “As technology evolves, federal partners, consumer groups and industry should continue to customize consumer-facing education on the components of a learning health system and the role of consumers in making it successful”.

## **SECTION D**

### **General Comments:**

- Section D should better emphasize the clinical-patient-family partnership. The section is very provider focused, even in sections where consumers and families have an important role to play.
- Section D technologies are very limited & restricted to existing health IT – new technologies, data liquidity, processing power and bandwidth will continue to push health IT in new directions.
  - Section D is potentially overwhelming. Providers report being overwhelmed with requirements today (MU, PQRS, ICD 10, etc.)
- Overall we suggest:
  - Focus more on outcomes and less on process.
  - Combining this Section with Section C will also help

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### D1. Organization/ Governance

#### 2015-2017 : Send, receive find and use a common clinical data set

**1. Call to action: Providers should participate in governance of interoperability at all levels, from regional efforts to nationwide coordinated governance.**

- This is an example where provider-consumer partnership is not reflected. Providers, **patients and families** should participate in governance of interoperability at all levels, from regional efforts to nationwide coordinated governance. This call to action for governance should be revised and applied to all the governance actions included in the document.

#### 2018-2020:Expand interoperable health IT and users

**2. Call to action: Providers should continue to provide input on the evolution of coordinated governance to support a learning health system.**

- See Call to Action 1 comment

#### 2021-2024:Achieve nationwide LHS

**3. Call to action: Providers should remain active in coordinated governance.**

- See Call to Action 1 comment

### D2. Providers embrace a Culture of Interoperability and work with vendors and other supporting entities to improve interoperability

#### 2015-2017: Send, receive, find and use a common clinical data set

**1. Call to action: Providers should routinely expect electronic access to *outside information* in the provision of care and engage with other providers to send, receive, find and use health information for their patients.**

The phrase “outside information” needs further clarification.

- New call to action: Vendors should build tools and interfaces that make all relevant information, including information from patients and other providers, easy to digest and act upon for providers, so it becomes a seamless part of their workflow. This will be essential – providers should not have to take a lot of time to wade through volumes of data (such as data from wearables, devices, and other provider types). We must develop tools that make data actionable for them.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

***2. Call to action: Providers should recognize that valuable clinical information about their patients may reside with patients or caregivers themselves and that they may need to incorporate that information into their decision making.***

The work group strongly supports this concept; it is critical to realizing meaningful partnerships between health care providers and patients. However- this must be focused on enabling providers to efficiently use this data- they will use it if it is both valuable and easy to use. Simply asking them to recognize the value is not necessary or effective here.

***3. Call to action: Providers and their organizations should embrace the use of enabling technologies such as publish/subscribe and query based exchange with single sign-on to minimize workflow barriers to interoperability.***

Strongly support this call to action.

Requirements should include:

- Patients able to send and create information to be shared.
- "Set and Forget" patients register the destination app of their choice so that all changes occurring (TOC) automatically sent to the app of their choice (Bluebutton Plus)
- Provenance
- "tamper proof seal"
- Equal level of assurance for all stakeholders to include transparent directories for public level secure email exchange

***4. Call to action: Providers and their organizations should ensure contracts and agreements that they sign and re-sign with technology developers include necessary requirements for interoperability, to ensure they can share and incorporate patient information***

The workgroup supports this notion. Part of ensuring "they can share and incorporate patient information" relates also to the fees charged by vendors. We are hearing increasing reports of vendor practices that create barriers to interoperability in the form of excessive fees. For example, we understand that some vendors are charging high fees to build interfaces and additional fees for the data that flows through those interfaces. ONC should consider a call to action such that vendors should not charge burdensome or excessive system fees for providers implementing or facilitating interoperability between data systems that support patient care.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### 2018-2020 Expand interoperable health IT and users to improve health and lower cost

#### ***5. Call to action: Providers should routinely access and use health information from other sources, including individuals, when making clinical decisions***

As noted previously this requires progress in areas such as provenance and “tamper proof seal.” Other sources should also include social and community-based services and supports that are important to the individual.

#### ***6. Call to action: Providers should routinely populate key data when E-prescribing in support of unambiguous prescription for verification, counseling, monitoring and activities of comprehensive medication management.***

#### ***7. Call to action: Providers and their organizations should work with necessary parties to configure systems to alert providers to the presence of relevant information from other sources and make it conveniently available to the provider.***

An alerting ecosystem should include consumer-facing health IT.

We also suggest combining this with the our earlier call to action regarding vendors building tools that make it easy for providers to digest and act upon other sources of information, including PGHD.

#### ***8. Call to action: Providers and their organizations should work with necessary parties to configure systems so that the presentation of information to providers is configurable based on use case, provider specialty and other characteristics, to facilitate usability and patient safety.***

One of the most essential use cases will be bi-directional, dynamic person-centered planning oriented around share health and care goals. This should be a priority use case because it is foundational to care coordination, person and family engagement, and interoperability. And many new and emerging advanced health models require it. And, if the planning process is used to better align patient engagement efforts with quality measurement, reporting and payment around those objectives, the end result will be a health care system that consistently, continuously and collaboratively works with individuals to document, measure, refine and communicate the objectives that are both meaningful to the patient and achievable by the delivery system.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### 2021-2024 Achieve a nationwide learning health system

**9. Call to action: Providers should practice in a new way, with a new culture of electronic health information sharing, access and use for both clinicians and institutions is firmly established.**

This call to action is foundational to achieving a transformed health care system and should be a goal. The Roadmap includes other strategies such as quality measurement, consumer access to and use of data, and payment which will drive toward this goal.

**10. Call to action: Providers should routinely use and have access to robust and clinically relevant decision support (e.g. for medication management).**

This should be implemented earlier in the timeline. Decision support should increasingly include the patient's values and preferences. Shared decision making with patients helps assure that evidence, patient concerns, values and directions are factored into the care. Progress should be made towards integrating shared decision making tools with clinical decision support.

**11. Call to action: Providers should regularly use and have access to the most relevant, integrated information, appropriate notifications.**  
This should include community living and social supports.

**12. Call to action: Providers should receive and provide continuous feedback to support the improvement of decision-making, care processes and outcomes.**

At this point if providers have started doing this in the previous time period, and quality measures and payment are aligned, this will be the natural outcome and may not require a separate call to action.

**13. Call to action: Providers should use new evidence-based guidelines and tools for care that are disseminated rapidly to providers through decision support and other timely and context-sensitive pathways.**

Strongly support this notion. This work should also be more explicitly connected to evolving quality measures and to the research enterprise.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### D3. Accurate Measurement

#### **2015-2017: Send, receive, find and use a common clinical data set to improve health and health care quality**

##### ***1. Call to action: Providers should leverage data beyond their internal systems for population health analytics and quality measurement (eQMs) including supporting value based payment models.***

This is an essential call to action, but we also lack a robust suite of eQMs that drive population health improvements. It is critical that a new call to action be added: Government should invest heavily in development of more advanced eQMs during this time period. This should also include harmonizing quality, population health, MU common data set and consumer information technology.

#### **2018-2020 Expand interoperable health IT and users to improve health and lower cost**

##### ***2. Call to action: Providers and other stakeholders should use standard metrics of interoperability to monitor and track improvement.***

Standard metrics for interoperability should also seek to capture the patient or family/designated caregiver's assessment of electronic sharing (i.e. if referred, was the patient's electronic information received and acted upon at the secondary provider's office by the time of the patient's visit? Were secure messages responded to in a timely fashion? Alternatively, ONC could assess the feasibility of measuring this primarily from the viewpoint of the patients and families. Providers already have measure fatigue, and consumers could be in a good position to provide insight.

Overall though, this effort should be focused less on interoperability and more on the purpose of interoperability – coordination and communication for health improvement. We recommend developing measures for care coordination, communication and health outcomes that require interoperability, instead of measuring interoperability itself. Focus on the outcome of interoperability by this time (2018-2020). Providers do not need more measures to report – they need better measures.

##### ***3. Call to action: Providers and other stakeholders should use standard metrics for interoperability and health outcomes to improve clinical care and processes.***

See above.

##### ***4. Call to action: Providers should be able to report on measures based on the most representative data available about each patient.***

Providers can report on measures today – the problem is that the eQMs we have today are not very advanced, and often don't reflect interoperability or longitude. Government should invest in more advanced eQMs and begin to slim down the focus on older process measures. Patient-reported measures should also be included.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### 2021-2024 Achieve a nationwide learning health system

**5. Call to action: Public and private stakeholders should objectively measure and value interoperability and information sharing as an indicator of care coordination, quality and efficiency.**

Payment for outcomes that require interoperability – like robust care coordination, person-centered planning, eVisits, reductions in duplicative testing, etc. will naturally drive interoperability and information sharing. These things must be paid for and measured. And as noted above, we do not need more measures of interoperability, we need better measures of the outcomes that interoperability is designed to support. The government must begin now to outline a strategy for development of eQMs, revision of current measure sets, and new payment approaches to incentive performance.

**6. Call to action: Providers should be able to report on measures based on more complete and consistent representative data about each patient.**

*See comments above*

### D4. Interoperability of processes and workflows

#### Workgroup Comment on this Entire Section:

We suggest re-evaluating this section entirely. Its focus on managing workflows for providers may not be necessary if, per the previous section, progress has been made in advancing measurement and payment. That should drive the essential workflows.

### 2015-2017 Send, receive, find and use a common clinical data set to improve health and health care quality

**1. Call to action: Providers should routinely leverage standards based health IT to support prioritized workflows including:**

- o Closed loop transitions of care*
- o Secure clinical communications*
- o Prior authorizations, medication co-pays and imaging appropriateness*
- o CPOE for services and diagnostic testing*
- o e-prescribing of controlled substances with concurrent availability of PDMP data*



## Consumer Workgroup Comments on Interoperability Roadmap, continued

### 2018-2020 Expand interoperable health IT and users to improve health and lower cost

2. *Call to action: Providers should engage with an expanded set of interoperable workflows, including:*

*o Plug-and-play clinical decision support services*

*o Electronic consultations*

*o Reporting to specialty society registries*

*o Reporting to value-based payment programs*

*o e-prescribing supported by complete medication fill history*

*o Discovery and incorporation of information from patient owned devices with tools for reconciliation and validation*

*o Recommendation of patients to relevant studies and trials*

*o Exchange of information to support comprehensive medication management and MTM services*

### 2021-2024 Achieve a nationwide learning health system

3. *Call to action: Providers should leverage a robust library of interoperable workflows to support care processes across the continuum of care, including tools for integration, reconciliation and validation of external information.*

## **D5. Training and maintenance of certification for providers**

***Workgroup is not Commenting on this Section***

### 2015-2017 Send, receive, find and use a common clinical data set to improve health and health care quality

1. *Call to action: Public and private stakeholders should incorporate interoperability into the training of new providers and continuing professional education.*

2. *Call to action: Professional specialty boards and other certifying bodies should agree on standards for interoperable registries and maintenance of certification.*

### 2018-2020 Expand interoperable health IT and users to improve health and lower cost

3. *Call to action: Public and private stakeholders should agree on a way in which to measure progress and competency of trainees is evaluated and scored using interoperable, standards based clinical information.*

4. *Call to action: Professional specialty boards and other certifying bodies should receive most of the information required from their diplomats through information exchanged in a standard format.*

5. *Call to action: Professional specialty boards should utilize standardized electronic data and formats to populate registries.*

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### **D6. Innovation and Generation of New Knowledge and Evidence**

#### **2015-2017 Send, receive, find and use a common clinical data set to improve health and health care quality**

***1. Call to action: Providers currently engaged in clinical research and quality improvement should work together with research institutions and other public and private stakeholders to establish a strategic plan for research and the generation of new knowledge.***

This call to action should include patients, families and their advocates, and the federal government should also play an important role given the large amount of federal funds going to research. In addition, we also recommend this or a related call to action includes strategies for involving patients and families in the research process, such as via the methodologies promoted by the Patient-Centered Outcomes Research Institute and its grantees.

#### **2018-2020 Expand interoperable health IT and users to improve health and lower cost**

***2. Call to action: Providers should further engage with the research community and should routinely offer patients and families participation in research and quality improvement programs.***

We also propose that providers, researchers, vendors, and developers use participatory research methods and engage consumers and patients in the co-design of digital health tools.

***3. Call to action: Community or region wide Institutional Review Boards should ensure that the appropriate patient protections are in place to conduct multi-sourced clinical research.***

#### **2021-2024 Achieve a nationwide learning health system**

Overall comment- given the large amount of federal funds dedicated to research, and the importance of federal funds and policy in promoting innovation, there should be a clearer role articulated for government.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

*4. Call to action: Researchers, providers and other stakeholders should accelerate and measure the pace of innovation and research, as well as the dissemination of new knowledge to improve health and care.*

*5. Call to action: Technology developers should enable patient-centered and future clinical research methods for accelerated deployment of research findings into clinical care.*

**Overall comment- given the large amount of federal funds dedicated to research, and the importance of federal funds and policy in promoting innovation, there should be a clearer role articulated for government.**

### **D 7. Transparency of Value and engagement of patients families and caregiver**

#### **2015-2017 Send, receive, find and use a common clinical data set to improve health and health care quality**

***1. Call to action: Providers should work together with purchasers of care to have access to patient out-of-pocket costs and those of payers and purchasers. Providers are engaged in regional efforts to measure quality and maximize value.***

Patients, families and their advocates should also be engaged in regional efforts to measure quality and maximize value.

***2. Call to action: Providers should offer and encourage access to medical records and secure communications with all patients and any family and caregivers who are authorized to engage in such communications.***

This seems to be redundant with earlier call to action in Section C.

***3. Call to action: Providers should support consumers in downloading or transmitting their health information to a destination of their choice.***

As noted earlier, the work group agrees but recommends that patient and family engagement include both the benefits and the risks of VDT, how-to, and appropriate safeguards. Providers will need support in this endeavor.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### 2018-2020 Expand interoperable health IT and users to improve health and lower cost

#### **4. Call to action: Providers should routinely utilize cost and quality data to make shared diagnostic and treatment planning decisions.**

The workgroup recommends that this call to action is reframed to promote integrating cost and quality data into shared decision making activities, platforms, etc. These should be shared decisions with patients and families. And consumers must be at the table to design how this occurs. The risk is that without consumer voices as partners in this process, consumers could perceive this to be about rationing or otherwise skimping on care.

#### **5. Call to action: Providers should work together with purchasers of care to develop, test and implement appropriate and credible indicators of value.**

This call to action should be harmonized with Section D3. In addition, there is a significant and necessary role for the federal government in stimulating this work. Years of effort on behalf of many stakeholders have shown that federal investment is needed to create credible, meaningful measures of value.

#### **6. Call to action: Providers should support consumer-facing services such as:**

- o Online scheduling***
- o Medication refill requests***
- o Electronic/Telehealth Visits***
- o Patient provided device data, screenings and assessments***
- o Informed consent and education modules***
- o Integration of patient generated health data in the medical record***
- o Patient-defined goals of care***
- o Shared care planning***

Timeline should be moved up for most of these items, and especially those whose foundation was created in MU2 today. Those that exist or will soon exist in the marketplace (online scheduling, med refills, patient goals of care, etc.) are essential to building consumer support and trust for health IT. ONC may want to consider pulling eVisits, telehealth and devices out separately, as much more work is needed there compared to other areas. We also recommend that this call to action as amended be integrated with Section C.

## Consumer Workgroup Comments on Interoperability Roadmap, continued

### 2021-2024 Achieve a nationwide learning health system

**7. Call to action: Providers should demonstrate the value of their care to those who receive and pay for it using objective, trusted metrics.**

**8. Call to action: Providers and individuals should work together to substantially reduce the burden of care coordination through patient-centered tools and sharing and use of electronic health information.**

As we commented earlier, we recommend including “services and supports coordination” in addition to “care” coordination. Further, by this point the burden should have been reduced already if other actions were completed. A measure of the outcome would be more appropriate here – that care is actually more coordinated, high-value, and patient- and family-centered.

**9. Call to action: Individuals should interact easily and seamlessly with their care team as they transition into and out of the health care system, communicating remotely with their care team as needed over time, rather than only in face-to-face care situations.**