Trans-Atlantic Business Council (TABC) Submission to Public stakeholder consultation on next phase of EU-US cooperation in eHealth/Health IT

Contact: Kara Sutton
Policy Director, TABC
ksutton@transatlanticbusiness.org

Roadmap Item: Collaborate with international stakeholders to develop and pilot a standardized approach for an international patient summary that can be exchanged internationally.

1. Do you agree with the proposed timetable and organisation of the work to create an international standard for a patient summary? *

- ○ Yes
- ◉ No

Although the timetable seems reasonable, we are concerned with the organization of the work. Specifically, the Roadmap does not include any reference or action item on interoperability and communication between medical devices, personal connected health products, EHRs and health IT systems. Whether devices are used in clinical, ambulatory, or home settings, medical device data is increasingly being relied upon at every point along the continuum of patient care. Continuous data derived by these solutions are becoming an integral part of the modern workflow and part of a patient's care record (or patient summary). Remote patient monitoring, telehealth, and mobile health (mHealth) technologies and their interoperability with EHRs and health IT systems should be considered part of the "international interoperability work-stream." Doing so would mirror policy and regulatory developments in both the United States and the European Union.

For example, in the U.S., the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) includes new programs that establish a Merit-based Incentive Payment System (MIPS) and an Alternative Payment Model (APM), that will transform the United States' healthcare system by shifting the Medicare system away from a quantity-based reimbursement payment model to one that is based on quality. In particular, the new MIPS program establishes Clinical Practice Improvement Activities stipulating a subcategory for care coordination and the use of remote monitoring or telehealth.

MIPS goes further by combining parts of other existing U.S. federal programs including the "Electronic Health Record Incentive Program - Meaningful Use" (Stage 1, Stage 2 and Stage 3). In its most recent iteration, the Stage 3 Final Rule, the Centers for Medicare and Medicaid Services (CMS), institutes an objective for "Coordination of Care Through Patient Engagement" which (among other things) seeks the incorporation of patient-generated health data ("PGHD") or data from a non-clinical settings into an eligible provider's EHR.

Building upon that rule, the Office of the National Coordinator for Health IT (ONC) recently announced a two-year project to develop a policy framework to identify best practices, gaps, and opportunities for progress in the collection and use of PGHD for research and care delivery through 2024. ONC is set to conduct pilots and test

implementation to refine the topics identified in the policy framework. ONC views the PGHD policy framework project as necessary towards a long-term policy solution for the successful implementation of PGHD requirements for a variety of federal government efforts including: the Federal Health IT Strategic Plan, the ONC Interoperability Roadmap, the 2015 Edition Certification Rule, Stage 3 of Meaningful Use, and the Obama administration's Precision Medicine Initiative ("PMI").

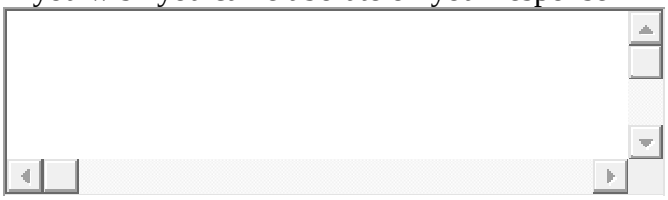
From a standards perspective, in September 2015, ONC released its Draft 2016 Interoperability Standards Advisory soliciting feedback on "interoperability needs" associated with communication between certain types of personal health devices and other information technology systems. Specifically, the ONC calls out health informatics standards under IEEE 11073 (that have also been recognized by the U.S. Food and Drug Administration and as referenced by the Continua Health Alliance – now the Personal Connected Health Alliance as acquired by the Health Information Management Systems Society or "HIMSS").

Taken individually, these regulatory and policy measures are remarkable. Taken collectively, it's undeniable the U.S. government has begun to embrace connected health technologies.

Similarly, interoperability between medical devices, personal connected healthcare products, and health IT systems, is not new to the European Union. For years, projects featuring the use of remote patient monitoring or telehealth have taken place throughout Europe including in regions such as Catalonia (Spain), Veneto (Italy), Bavaria (Germany), Île-de-France (France) and in countries like Denmark, the United Kingdom, Hungary, and Poland.

In summary, the Roadmap and its related timeline and organization specific to the "International Interoperability Work-Stream" should consider interoperability between medical devices, personal connected healthcare products, EHRs and health IT systems that enable remote patient monitoring and telehealth.

If you wish you can elaborate on your response



2. Are there areas of technical standards work missing that would be important to the success of the international patient summary record work? *

There are areas of technical standards work missing that would be important to the success of the Roadmap.

Similar to the answer in "Question 1" - The Roadmap and its related timeline and organization do not adequately consider interoperability and communication between medical devices, personal connected healthcare products, EHRs and health IT systems – nor do they adequately address the related standards and implementation specifications.

It is encouraging that the Roadmap states, "*For example, the work products of the latest version of the roadmap could feed into new activities that recognize the importance of developments such as software designed for mobile and medical devices, and that continue to empower patients to contribute their own data into the healthcare ecosystem. To that end, we will continue to consult with stakeholders on how these might be included in the roadmap.*"

We recommend assessing technical standards and implementation specifications for interoperability and communication between medical devices, personal connected healthcare products, EHRs and health IT systems.

3. What are the best use cases for the International Patient Summary to address at a global scale (e.g., emergency, disaster, migration, tourism)? *

The delivery of healthcare happens in motion, virtually anywhere and at any time, whether during an emergency, a disaster, migration or tourism. Data portability allows patients to upload patient generated health data or view, download and transmit that information, or be able to securely communicate data to a medical professional or a non-medical healthcare provider. Remote patient monitoring technologies, telehealth, mobile health (mHealth), and health IT, play an increasingly vital role in the global healthcare system and should be included as part of the Roadmap.

Health IT is a broad ecosystem of data-driven technologies. Health IT is not solely EHR technologies but encompass a broad array of health and medical products, devices, apps and services that touch patients; electronically capturing and generating specific physiological data points about a person's health. To solely focus on a handful of use cases, or only EHRs and EHR systems, ignores the interconnected value of health IT and importantly disregards significant capabilities available to patients. Although health IT alone cannot heal a patient, when incorporated into the healthcare delivery system and utilized by care providers, it can lead to better decisions, avoid patient errors, increase efficiency, and help better understand individual and population health.

Roadmap Item: Identify and understand current privacy and security laws and practices surrounding the exchange of health data for the purposes of clinical care across borders.

4. What specific privacy and security requirements or practices could improve and allow for the exchange of health data for the purposes of clinical care across borders? *

We believe that robust data protection and security will be fundamental requirements for the success and the widespread deployment of an eHealth/Health IT ecosystem. Current HIPAA Security Rule and EU Member State sectoral security provisions will need to be adapted in line with initiatives such as the recently announced Cybersecurity National Action Plan (CNAP) in the US and the upcoming EU Public-Private Partnership on Cybersecurity. Moreover, we welcome EU initiatives to develop industry-led, EU-wide codes of conduct (such as the ongoing work to create a privacy code of conduct on mHealth apps and the recently launched working group to develop guidelines for health apps data to be reliably linked to EHRs) and certification mechanisms that can enhance citizens' trust in eHealth services and applications and facilitate their effective uptake in clinical practice, including across borders.

IT Workforce Development

Roadmap Item: Consult with qualified stakeholders to determine the skills and competencies required by each role in each setting, at each level of responsibility (in the US and EU).

5. Which health IT competencies and other skills are important for the development of the following healthcare workers? *

- ☐ Clinical practitioners (doctors, nurses, etc.)
- ☐ Health Informatics professionals
- ☐ Non-clinical and administrative staff
- ☐ IT professionals coming to work in the healthcare environment

Innovation Ecosystems (for eHealth/Health IT)

Roadmap Item: Establish an EU-US working group to identify priority areas for collaboration (in innovation ecosystems for eHealth/Health IT)

6. Do you consider the next 18 months to be a higher priority for collaboration among the EU and US or the next 3 to 4 years? *

Within the Transatlantic eHealth/Health IT Innovation Ecosystems Work-stream, there needs to be short-term (within 18 months) actions, outcomes and deliverables, as well as longer-term (3 to 4 year) objectives. We encourage the formation and establishment of an EU-US working group to identify priority areas for collaboration – specifically in the

areas of remote patient monitoring and telehealth. This Working Group can assess the latest technological capabilities in eHealth/Health IT and the growing importance of mobile medical devices and mobile health products including software and apps.

7. Which EU and US regions and cities do you consider likely candidates for building transatlantic innovation ecosystems partnerships over the next 12 to 18 months? *

Those regions/states with the most interest, technical and economic resources should be considered.