



**Comments of the Trans-Atlantic Business Council on the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements**

To the U.S. National Coordinator, Karen DeSalvo:

The Trans-Atlantic Business Council (“TABC”) appreciates the opportunity to submit comments to the Department of Health and Human Services’ Office of the National Coordinator for Health Information Technology (“ONC”) on the February 26, 2014-published proposed proposals for the next edition (the “2015 Edition”) of electronic health record (“EHR”) technology certification criteria for eligible professionals (“EPs”), eligible hospitals, and critical access hospitals (“CAHs”). We appreciate the opportunity to comment on ONC’s efforts on the proposed regulatory approaches, including the voluntary nature of certification criteria in order to qualify for Medicare or Medicaid electronic health record (“EHR”) incentive payments.

The Trans-Atlantic Business Council (TABC) was created in 2012 as the result of a merger between the TransAtlantic Business Dialogue (TABD) and European-American Business Council (EABC). TABC is a cross-sectoral business association which creates a stronger business voice for its 70 plus member companies based in the EU and US. It advocates for the timely development of a comprehensive transatlantic agreement that further liberalizes trade and investment and promotes greater regulatory convergence, and continues engagement with forums such as the Transatlantic Economic Council (TEC).

TABC member companies represent many industrial sectors including healthcare and medicine. Our members develop products and services in health information technologies, converged wireless medical devices, and pharmaceutical life sciences. While ONC has issued a proposed template for public comments and responses, TABC finds it more useful to provide unstructured comments and we appreciate ONC’s flexibility to accept comments in whatever format is most suitable to stakeholders.

Generally, several new certification criterion and references throughout the proposed rule seem to focus on a user’s ability to access, provide and encourage the utilization of patient data in ways that may emphasize connected e-Care – that is the delivery of healthcare in motion, virtually anywhere and at any time. References include patient-specific education resources, implantable device lists, transitions of care, incorporation of laboratory tests and values/results, data portability and a

strengthened ability to view, download and transmit to third parties. However, more needs to be done.

Health IT is a broad ecosystem of data-driven technologies that increasingly rely on advanced remote medical products that are broadband enabled (through either wired, wireless or mobile means). Health IT is not solely EHR technologies but encompasses a broad array of health and medical products, devices, mobile health applications and related digital services that actually touch patients; electronically capturing and generating specific physiological data points about a person's health.

In December 2010, the U.S. Department of Health and Human Services signed a Memorandum of Understanding (MoU) with the European Commission on health related information and communication technologies. Unfortunately, the MoU has failed to make transatlantic medical device interoperability a reality.

Remote patient monitoring technologies such as telemedicine, telehealth, e-Care and mobile health (mHealth) play an increasingly vital role in the global healthcare system and should be included as part of the roadmap between the U.S. and the EU. To exclusively focus on Certified EHR, Certified EHR systems and the exchange of data between these systems ignores the interconnected value of health IT and importantly disregards significant aspects of the patient. Although health IT alone cannot heal a patient, when incorporated into the healthcare delivery system it can enable eligible care providers to make better decisions, avoid patient errors, become more efficient, and understand individual and population health more effectively.

TABC offers the following considerations for the 2015 CEHRT:

➤ **Technical Capabilities**

- Health IT (HIT) is not limited to the exchange of EHR's, but rather is a broader ecosystem that begins with data captured electronically from a patient, derived through interoperable remote patient monitoring devices, sensors, applications and products, and then transmitted through common specifications to populate the patient's EHR.
- Broaden focus to include remote patient monitoring (RPM) - electronic self-management tools that are interoperable, commercially available, home-based medical devices, sensors, applications and products that communicate via wired, wireless or mobile interfaces.
- Develop interoperable standards and specifications for HIT systems including remote patient monitoring and EHR.
- Develop transatlantic certification of EHR and HIT products.

➤ **Development and use of Data Standards**

- Establishment of chronic disease data standards for research, treatment, patient safety and to streamline data collection.
- Improve population health through leveraging EHRs to capture and report faster and more reliably.
- Accelerate and implement standard terminologies services and mapping tools to advance trans-border communication.

- Endorse and stimulate standards harmonization process (ANSI/CEN/CENELEC/ISO/IEEE) relevant to the field.
- **Disease prevention and health promotion services**
  - Engage patients and families in their care by offering electronic self-management tools and ensuring the capability to upload and incorporate patient-generated biometric home monitoring data into EHR's.
  - Foster patient engagement through web based tools and other portals.
  - Support the transition of care through RPM from hospital or acute setting to the home.
- **Putting the Patient First**
  - Identify high-risk patients for initial increased attention through the use of remote patient monitoring technology.
  - Digitize discharge summaries.
  - Provide patients with electronic copies of clinical summaries.
  - Implement the most applicable form of remote patient monitoring technology at the point of discharge and thereafter as applicable.
  - Identify high-risk patients for initial increased attention through the use of remote patient monitoring technology.
  - Build interactive mechanisms to understand how the patient is feeling post discharge.
  - Focus on patient education to eliminate obstacles.

We thank ONC for their consideration of our comments which reflect the considered input from a diverse set of TABC member companies.

Best regards,



**Tim Bennett**  
Director-General & CEO  
Trans-Atlantic Business Council