



TELECOMMUNICATIONS
INDUSTRY ASSOCIATION

1320 N. Courthouse Rd., Suite 200
Arlington, VA 22201 USA
www.tiaonline.org

Tel: +1.703.907.7700
Fax: +1.703.907.7727

Submitted via CNECT-GREEN-PAPER-mHealth@ec.europa.eu

July 3, 2014

European Commission
DG Communications Networks, Content & Technology
Avenue de Beaulieu/Beaulieulaan 31
Unit H1, Health & Well-being
Brussels 1049 - Belgium

Dear Sir/Madam:

The Telecommunications Industry Association (TIA) hereby submits comments in response to the European Union's (EU) public consultation on its Green Paper on mobile Health.¹ We appreciate the EU's request for input towards identifying the right way forward to unlock the potential of mobile health in the EU.

TIA is a trade association representing nearly 400 global manufacturers, vendors, and suppliers of information and communications technology (ICT), and engages in policy efforts specific to health ICT to promote a modern healthcare system that leverages innovative technologies to transform the way care is delivered and consumed. Many of TIA's member companies develop, manufacture, and supply health information technologies and medical devices, producing the tools that allow patients and health care providers to connect virtually anytime, anywhere.

¹

<http://ec.europa.eu/digital-agenda/en/public-consultation-green-paper-mobile-health>

Below, TIA provides input to certain questions posed in the Green Paper:

Which specific security safeguards in mHealth solutions could help to prevent unnecessary and unauthorised processing of health data in an mHealth context?

Generally, data security policies should allow for continued success of innovative technologies in the global marketplace, enabled through (1) participation in public-private partnerships to improve coordination and risk management; and (2) the development of internationally-used standards and best practices, assurance programs, and conformity assessment regimes. We urge the EU to recognize that the global nature of the ICT industry requires a global approach to address data security concerns, and that a global supply chain can only be secured through industry-driven adoption of best practices and global standards. Furthermore, many countries look to the EU to set an example for effective data security policies.

To avoid unnecessary impediments to transatlantic trade, any approach taken by the EU to address security safeguards should involve: international cooperation; significant engagement with global industry; reliance on voluntary, open, and consensus-based standards; and, avoidance of policies that would put governments in a position to determine the future design and development of technology.

How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?

TIA urges the EU to provide maximum clarity to stakeholders on the difference between those devices which are and are not considered medical devices. Flexible, bottom-up approaches using appropriately granular risk assessments will provide much-needed certainty in the mHealth field generally, and will facilitate competition and innovation. Factors that should be included in any current and future risk-based regulatory approach to health IT should promote innovation and protect patient safety by including:

- Clear and common definitions;
- Answers to key questions that increase regulatory clarity;
- Technology neutrality;



- A holistic approach when balancing risks and benefits, under a “prescriptive/inclusionary” focus; and
- Clear regulation and guidance on accessories.

Further, TIA strongly urges for the use of enforcement discretion for ICTs which may meet the EU’s definition of medical device, but which pose little or no potential risk to consumers. Such an approach would be consistent with the FDA’s mobile medical applications guidance document, which made clear that certain mobile applications subject to FDA enforcement which posed little or no risk to consumers would qualify for this discretion, because the resources spent on regulating them outweigh the degree of their risk to consumers.² Such an approach was heavily favored in the mobile medical applications context by stakeholders, and has provided greater certainty in the application of FDA regulations since the release of the document in September of 2013.

Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?

First, TIA would like to highlight the Green Paper’s assertion that adoption of mHealth in the EU is lacking. Telehealth services have numerous benefits, including the transmission of vital signs as part of care plans for chronic disease patients’ electronic health records (“EHRs”); the transmission of important medical device data, text and images for specialist diagnoses such as X-rays, MRIs, and CAT scans; video conferencing for telemedicine or training; and even timely access to emergency medical providers to save lives. These benefits are especially important for rural areas, where telemedicine consultations with specialists such as pediatric critical-care physicians have been shown to improve the quality of care for seriously ill and injured children treated in rural emergency rooms.³ In addition to the benefits to those most directly touched by enhanced telehealth services – the patients – there are other residual benefits to our society

² See Food and Drug Administration, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff* (2013) at 13, available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>.

³ See, e.g., Dharmar, et al, Impact of of Critical Care Telemedicine Consultations on Children in Rural Emergency Departments, *Journal of Critical Care Medicine* (Aug, 7, 2013), doi: 10.1097/CCM.0b013e31828e9824.

by decreasing the cost of healthcare systems. For example, remote patient monitoring – just one aspect of telehealth services – is expected to save \$36 billion globally by 2018.⁴

Not only has clinical evidence demonstrated that interoperable remote monitoring improves care, reduces hospitalizations, helps avoid complications and improves satisfaction, particularly for the chronically ill,⁵ but the monitoring of patient-generated health data (PGHD) through remote monitoring solutions can enhance patient care and raise accountability by healthcare providers,⁶ as well as engage patients in their own care, leading to improved lifestyle choices and improve overall health.⁷ It is important for the EU to give providers in the EU the certainty that, in their use of remote monitoring solutions, all forms of patient care, including those using remote monitoring technologies, are appropriate.

What do you think should be done in addition to the proposed actions of the eHealth Action Plan 2012-2020 in order to increase interoperability of mHealth solutions?

Generally, the development of voluntary, consensus-based standards remains a critically important element for innovation and the continued commercial success of the ICT sector in the EU. The EU should strive to develop an effective, common approach to conforming standardization policies that should be globally influential in promoting market- driven standards that are based on transparency, technical merit, and openness to all interested stakeholders. This alternative model is preferable to the proliferation of technical regulations

⁴ See Juniper Research, *Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018* (rel. Jul. 17, 2013), available at http://www.juniperresearch.com/reports/mobile_health_fitness.

⁵ See, e.g., U.S. Agency for Healthcare Research and Quality (“AHRQ”) Service Delivery Innovation Profile, *Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs* (last updated Feb. 6, 2013), available at <http://www.innovations.ahrq.gov/content.aspx?id=3006>.

⁶ See NeHC, *Patient Generated Health Data Introduction and Current Practices: Report to the HIT Policy Committee Consumer Empowerment Workgroup by the Technical Expert Panel Convened by National eHealth Collaborative on behalf of the Office of the National Coordinator for Health Information Technology* (Jul. 18, 2013), available at <http://www.nationalehealth.org/blog/patient-generated-health-data-technical-expert-panel-presents-initial-findings>.

⁷ See, e.g., Sanjena Sathian, “The New 21st Century House Call,” *Boston Globe* (July 29, 2013), available at <http://www.bostonglobe.com/lifestyle/health-wellness/2013/07/28/century-house-call/tdupWvOQl6b3dKdKcEgdGM/story.html>.



that rely on indigenously developed standards that create market access barriers, undermine interoperability, and impose additional costs for global businesses. International cooperation should be a priority in mHealth in order to prevent the possibility of geographic-specific standards, technical regulations, or requirements, which would put at risk the global competitiveness and innovation of the ICT sector.

Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records? And if yes by whom and how?

The voluntary adoption and use of international and open standards is a recommended priority that would promote effective and efficient technology and innovation in the mHealth marketplace. The use of such standards for interoperability between remote patient monitoring devices and EHRs would leverage the broader information and communications technology industry that has flourished globally through ubiquitous interoperable mobile devices, systems and networks. It would also enable systemic engagement between patients, health care providers, and other stakeholders. Indeed, such voluntary industry standards – along with consensus on specifications for interoperability between remote monitoring systems and EHRs – already exist and are currently being used in deployed products. TIA recommends that the EU tie incentive payments to exclusively use interoperable EHR products that guarantee useable data regardless of vendor.

Could you provide specific topics for EU level research & innovation and deployment priorities for mHealth?

TIA believes that an informed approach by the EU towards mHealth research and development could be guided by several existing programs in the US which were created to explore alternative payment solutions including technological advancements such as the use of remote monitoring solutions. For example:

- The CMS Innovation Center’s (“CMMI”) Independence at Home pilot program,⁸ which is using remote monitoring and mobile diagnostic technologies;

⁸ See <http://innovation.cms.gov/initiatives/independence-at-home/>.

- The CMMI's Comprehensive ESRD Care initiative,⁹ which is examining the benefits of remote monitoring to those suffering from end stage renal disease ("ESRD"); and
- The Veteran's Administration Home Based Primary Care program,¹⁰ which has comprehensively shown an improvement in quality of care, as well as cost reductions, for patients with multiple chronic conditions.

Furthermore, TIA notes that there are extensive clinical studies from the US for the EU to consult, including in the areas of: chronic condition management; heart failure management; diabetes management and medication adherence for chronic conditions meet stringent review standards and demonstrate strongly the benefits of non-synchronous telehealth and remote patient monitoring. Below, we list clinical trials under each of these categories for CMS' consideration:

CHRONIC CONDITION MANAGEMENT

Veterans Administration: Study Size: Over 17,000 patients.

"Routine analysis of data obtained for quality and performance purposes from a cohort of 17,025 CCHT patients shows the benefits of a 25% reduction in numbers of bed days of care, 19% reduction in numbers of hospital admissions, and mean satisfaction score rating of 86% after enrolment into the program. The cost of CCHT is \$1,600 per patient per annum, substantially less than other NIC programs and nursing home care. VHA's experience is that an enterprise-wide home telehealth implementation is an appropriate and cost-effective way of managing chronic care patients in both urban and rural settings." "Care Coordination/Home Telehealth: the systematic implementation of health informatics, home telehealth, and disease management to support the care of veteran patients with chronic condition" [Darkins A, Ryan P, Kobb R, Foster L, Edmonson E, Wakefield B, Lancaster AEs, Telemed J E Health. 2008 Dec;14(10):1118-26. doi: 10.1089/tmj.2008.0021.] <http://online.liebertpub.com/doi/pdf/10.1089/tmj.2008.0021>

Primary Care E-Visit v. Physician Office Visit: Study Size 8,000 Office and E-Visits

From The Washington Post, 1/21/2013: "A new study suggests that "e-visits" to health-care providers for sinus infections and urinary tract infections (UTIs) may be cheaper than in-person office visits and similarly effective." [Ateev Mehrotra, MD; Suzanne Paone, DHA; G. Daniel Martich, MD; Steven M. Albert, PhD; Grant J. Shevchik, MD, JAMA Intern Med. 2013;173(1):72-74. doi: 10.1001/2013. jamainternmed.305] <http://archinte.jamanetwork.com/article.aspx?articleid=1392490>

⁹ See <http://innovation.cms.gov/initiatives/comprehensive-ESRD-care/>.

¹⁰ See http://www.va.gov/geriatrics/guide/longtermcare/home_based_primary_care.asp.

Randomized Control Trial of Telehealth and Telecare: Study Size 6,191 patients, 238 GP practices

“The early indications show that if used correctly telehealth can deliver a 15% reduction in A&E visits, a 20% reduction in emergency admissions, a 14% reduction in elective admissions, a 14% reduction in bed days and an 8% reduction in tariff costs. More strikingly they also demonstrate a 45% reduction in mortality rates.” [Source: “Whole System Demonstrator Programme, Headline Findings – December 2011”, Department of Health, United Kingdom] http://www.telecare.org.uk/sites/default/files/file-directory/secure_annual_reports/Publications/Effect%20of%20Telehealth%20on%20use%20of%20secondary%20care%20and%20mortality%20findings%20from%20the%20WSD%20cluster%20randomised%20trial.pdf

HEART FAILURE MANAGEMENT

Remote Patient Monitoring of Heart Failure Patients, Meta analysis: Study Size 4,264 patients

“Remote monitoring programmes reduced rates of admission to hospital for chronic heart failure by 21% (95% confidence interval 11% to 31%) and all cause mortality by 20% (8% to 31%); of the six trials evaluating health related quality of life three reported significant benefits with remote monitoring.” [Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis, Robyn Clark, Sally Inglis, Finlay McAlister, John Cleland, Simon Stewart, MJ (British Medical Journal), doi:10.1136/bmj.39156.536968.55 (published 10 April 2007)]

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1865411/>

Remote Patient Monitoring of Heart Failure Patients, Meta analysis: Study Size 6,258/2,354 Patients

“RPM confers a significant protective clinical effect in patients with chronic HF compared with usual care.” [J Am Coll Cardio: 2009;54:1683-94]

<http://content.onlinejacc.org/article.aspx?articleid=1140154>

Telehome Monitoring Program: 1,000 Patients Enrolled

“Research at the Heart Institute has shown telehome monitoring at the Heart Institute has cut hospital readmission for heart failure by 54 percent with savings up to \$20,000 for each patient safely diverted from an emergency department visit, readmission and hospital stay.” [University of Ottawa Heart Institute, February 24, 2011, Press Release]

[http://www.heartandlung.org/article/S0147-9563\(07\)00084-2/fulltext](http://www.heartandlung.org/article/S0147-9563(07)00084-2/fulltext)

Remote Patient Monitoring at St. Vincent's Hospital:

"Impact: In less than two years, preliminary results show that the care management program implemented by St. Vincent Health and facilitated by the Guide platform reduced hospital readmissions to 5 percent for patients participating in the program – a 75 percent reduction compared to the control group (20 percent), and to the national average (20 percent)." [St. Vincent's Hospital Reduces Readmissions by 75 percent with a Remote Patient Monitoring-Enabled Program, Case Study by Care Innovations, an Intel GE Company]

http://www.careinnovations.com/data/sites/1/downloads/Guide_product/guide_stvinc ent_profile.pdf

DIABETES MANAGEMENT:

Mobile Phone Personalized Behavior Coaching for Diabetes: Study Size 163 patients over 26 Practices

"Conclusions – The combination of behavioral mobile coaching with blood glucose data, lifestyle behaviors, and patient self-management individually analyzed and presented with evidence-based guidelines to providers substantially reduced glycated hemoglobin level over 1 year." [Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control, Charlene Quinn, Michelle Shardell, Michael Terrin, Eric Barr, Soshana Ballew, Ann Gruber-Baldini, Diabetes Care. Published Online July 25, 2011]

<http://care.diabetesjournals.org/content/34/9/1934.long>

Mobile Phone Diabetes Management: Study Size 30 patients from 3 group practices

"Conclusions: Adults with type 2 diabetes using WellDoc's software achieved statistically significant improvements in A1c. HCP and patient satisfaction with the system was clinically and statistically significant." [WellDoc™ Mobile Diabetes Management Randomized Controlled Trial: Change in Clinical and Behavioral Outcomes and Patient and Physician Satisfaction, Charlene Quinn, Suzanne Sysko Clough, James Minor, Dan Lender, Maria Okafor, Ann Gruber-Baldini, Diabetes Technology & Therapeutics, Vol 10, Number 3, 2008, pps 160-168]

<http://online.liebertpub.com/doi/pdf/10.1089/dia.2008.0283>

MEDICATION ADHERENCE FOR CHRONIC CONDITIONS: 50 patients

"There was a trend toward increased prescription refill rates with the use of the Pill Phone application and a decrease after the application was discontinued" [Case study titled: "Medication Adherence and mHealth: The George Washington University and Wireless Reach Pill Phone Study", Study designed, conducted and analyzed by George Washington University Medical Center; Qualcomm Wireless Reach Initiative was the

primary funder of this study]

<http://www.qualcomm.com/media/documents/files/wireless-reach-case-study-united-states-pill-phone-english-.pdf>

Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?

The digitization of health care is a major growth area for “machine-to-machine” (M2M) communications that enable the timely sharing of PGHD. There are direct societal benefits to enhanced health ICT M2M communications, such as providing hospitals with the location of critical mobile equipment, reducing the time it takes health care workers to access that equipment in an emergency, increasing the efficiency of emergency services, and remote monitoring in home settings, among other direct benefits. All of these described benefits are effects that directly correlate with the inclusion of PGHD, particularly via mobile medical applications, when integrated into and allowed by health care systems.

Transatlantic cooperation in the areas of eHealth and health ICT are already taking place under the auspices of the Transatlantic Economic Council.¹¹ While current areas of cooperation focus primarily on “electronic health records” (EHRs) interoperability and workforce development, there is an opportunity to expand this regulatory cooperation to address the full potential of eCare, including remote monitoring and PGHD. Based on the potential benefits that remote monitoring and PGHD can provide to the hundreds of millions living in both the US and EU, TIA believes in expanding beyond simply the interoperability of EHRs to realize the potential benefits of the fully-supported health ICT ecosystem – translating to a broadening of focus to the full eCare concept in both governments and their collaborative efforts. This broader focus would be a noteworthy step towards encouraging innovation and investment into new technologies throughout and between the US and EU that will improve care, reduce hospital visits, and save lives. For example, TIA believes that there are various specific steps under the broader TTIP concept of regulatory compatibility and cooperation that should also be addressed to streamline regulatory compliance, particularly for next generation medical applications.

¹¹ See [Transatlantic eHealth/health IT Cooperation Roadmap](#), February 2013.



TELECOMMUNICATIONS
INDUSTRY ASSOCIATION

1320 N. Courthouse Rd., Suite 200
Arlington, VA 22201 USA
www.tiaonline.org

Tel: +1.703.907.7700
Fax: +1.703.907.7727

Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to boost mHealth deployment?

TIA strongly encourages the EU to, past the Green Paper, continue to strive to identify and implement incentives for the widespread deployment of mHealth solutions. For example, incentives in the form of reimbursements for the effective implementation of enhanced technological mHealth solutions that utilize remote monitoring should be considered by the EU, in the same vein as the US' Meaningful Use incentive program.



TELECOMMUNICATIONS
INDUSTRY ASSOCIATION

1320 N. Courthouse Rd., Suite 200
Arlington, VA 22201 USA
www.tiaonline.org

Tel: +1.703.907.7700
Fax: +1.703.907.7727

TIA, on behalf of hundreds of global health IT manufacturing and vendor community members, requests that its views in this matter be considered and stands ready to work with the EU as it moves forward towards realizing the potential of mHealth. Please contact the undersigned if we can be of more assistance.

Respectfully submitted,

TELECOMMUNICATIONS INDUSTRY ASSOCIATION

By: /s/ Brian Scarpelli

Brian Scarpelli
Director, Government Affairs

David Gray
Associate, Government Affairs

TELECOMMUNICATIONS INDUSTRY ASSOCIATION

1320 Court House Road
Suite 200
Arlington, VA 22201
United States of America
(703) 907-7700

July 3, 2014