



TELECOMMUNICATIONS
INDUSTRY ASSOCIATION

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June 16, 2014

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
United States House of Representatives
Washington, DC

The Honorable Henry Waxman
Ranking Member
House Energy and Commerce Committee
United States House of Representatives
Washington, DC

The Honorable Joe Pitts
Chairman, Subcommittee on Health
House Energy and Commerce Committee
United States House of Representatives
Washington, DC

The Honorable Frank Pallone
Ranking Member, Subcommittee on Health
House Energy and Commerce Committee
United States House of Representatives
Washington, DC

Dear Chairmen and Ranking Members:

The Telecommunications Industry Association (TIA) hereby submits comments in response to the House Energy and Commerce Committee Subcommittee on Health's hearing titled "Telehealth to Digital Medicine: How 21st Century Technology Can Benefit Patients."

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. TIA would like to applaud the Energy & Commerce Committee for launching an initiative aimed at accelerating the discovery, development, and delivery of new treatments and cures to patients, and we thank the Committee for this opportunity to provide comments.

I. Encouraging Investment & Innovation



The United States' propensity for innovation has allowed us to maintain a global competitive edge and reap the economic benefits. As other countries seek to emulate our success and commit more resources to research and development, it is imperative that the United States maintain its leadership role as a hub for innovation. For this to continue, we must have effective policies in place that facilitate investment and innovation, and a regulatory framework that provides predictability and reduces barriers to innovation.

**a. The Health Care System of the Future Should Realize the Potential of
Telehealth and Remote Patient Monitoring**

A modern, 21st century healthcare system must leverage innovations in communications technologies. Innovative technologies are needed that connect patients, health care providers, and medical professionals virtually anywhere, and facilitate ongoing care and treatment wherever and whenever it is needed. However, outdated regulations that have restricted the use of telehealth have long been a hindrance to progress in this space. As a notable example, Section 1834(m) of the Social Security Act has resulted in arduous restrictions on telehealth services (*see* 42 CFR § 410.78). The ICT manufacturer, vendor, and supplier community urges for Congress to work towards realization of a connected healthcare system by removing barriers to the utilization of advanced technologies. For example, a broad cross-section of stakeholders in the healthcare space have joined TIA in urging for newly-confirmed HHS Secretary Burwell to waive 1834(m) restrictions on Accountable Care Organizations in the Medicare Shared Savings Program.¹

In addition, the state-by-state approach to the regulation of physicians ignores the nature of advanced communications technologies that allow for treatment services across state lines. We call on Congress to remove the multiple state licensing requirements for physicians to provide telemedicine services. By eliminating these barriers, Medicare physicians can connect virtually with patients nationwide to bring the full benefits of telemedicine to seniors and those with mobility impairments.

The known benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the

¹ See <http://bit.ly/1na1UrA>.



chronically ill.² In addition, use of virtual chronic care management by the Department of Veterans Affairs resulted in a substantial decrease in hospital and emergency room use.³

Remote patient monitoring of patient-generated health data (PGHD) must be utilized for any health care system to realize its full potential. The National eHealth Collaborative (“NeHC”) has defined PGHD as “Health-related data created, recorded, gathered, or inferred by or from patients or their designees to help address a health concern.”⁴ Involving this data will engage patients in their own care, can lead to improved lifestyle choices and improve overall health.⁵ There are also significant potential for cost savings, with a recent study predicting that remote monitoring will result in savings of \$36 billion globally by 2018, with North America accounting for 75% of those savings.⁶ Policies must be in place that enable greater use of these dynamic solutions and promote greater development and opportunities for health care deliver; for example, we strongly urge Congress to examine all opportunities to remove the arduous burdens of Section 1834(m).

We urge Congress to allow for the full range of available technologies available to improve quality, safety, efficiency, and reduce health disparities by engaging patients and families while improving care coordination, population and public healthcare. While national and global efforts to develop, integrate, and utilize innovative technologies that enable eHealth and telemedicine have allowed this industry to mature, we must continue looking for ways to maximize the potential of health ICT. Regulations and policies should reflect the dynamic and transformative nature of these technologies, and shouldn’t stifle innovation. Current areas of focus, particularly on the agency level, remain on electronic health records (EHRs) and EHR interoperability. Though Meaningful Use (MU) requirements seek to engage patients and their

² 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>.

³ See Darkins, et al., *Telemed J E Health*. 2008 Dec. 14 (10) 1118-26. doi: 10.1089/tmj.2008.0021.

⁴ See NeHC, *Patient Generated Health Data White Paper* (Apr. 2012) at 2-3, available at http://www.nationalehealth.org/ckfinder/userfiles/files/PGHD%20White%20Paper_April%202012.pdf.

⁵ 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/tdupWvOQI6b3dKdKcEgdGM/story.html>.

⁶ 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.



families, the important information captured by a patient's home medical device has yet to become a part of the care record. TIA has long urged CMS that MU criteria should adequately account for the full range of products, such as health IT medical remote monitoring products that could further CMS' goals under Meaningful Use. Innovative technologies such as these can provide timely and crucial information to EHR systems, and should be used to directly capture data from their patients; once data is captured from a patient through medical remote monitoring, that data should be used to populate an EHR, which will follow a patient along the continuum of care.

And while there remains a final opportunity to improve health outcomes through Meaningful Use Stage 3 in 2014, there is a true need for federal priorities to address the full potential of the health information technology ecosystem which is comprised of many technologies, including medical remote monitoring products that are enabled with wired, wireless and mobile ICT. Based on the potential benefits that remote monitoring and PGHD can provide to countless Americans, we encourage Congress to approach efforts to advance healthcare past interoperability of EHRs, and to fully support a connected health ICT ecosystem. Embracing the diversity of solutions will allow for innovative improvements at each stage along the continuum of care. Consciously taking a broader focus as we describe above would be a noteworthy step towards encouraging innovation and investment into new technologies that will improve care, reduce hospital visits, and save lives.

In addition, TIA believes there is an excellent opportunity for CMS to remove arduous restrictions on healthcare service providers through its forthcoming revision of the 2015 Physician Fee Schedule. Specifically, chronic care management codes should be widely updated to contemplate telehealth and remote monitoring as an eligible service. In a filing to CMS in late 2013,⁷ TIA explained that it strongly believes that including remote monitoring solutions as a mandatory supplemental benefit will serve as a significant step towards modernizing the delivery of care by extending beyond the walls of the hospital room, and we urge you to consider these priorities elaborated on in that filing.

b. The United States Must Make Investment in Advanced Medical Device Technologies a National Priority

⁷ See <http://bit.ly/1qbHvaw>.



Decades of robust investment in the discovery, development, and delivery of new treatments and cures has made the U.S. a global leader in medical device innovation. Our successes have driven global competition and now other countries are increasing their own contributions to research and development. In order to maintain our status as a global leader the U.S. must make investments in medical research a national priority. From 2007 to 2012, U.S. investment in biomedical R&D dropped from \$131.3 billion to \$119.3 billion, a -1.9% compound annual decline. During the same period, the Asia-Pacific region increased spending increased from \$41.1 billion to \$62 billion, including a 5.7% compound annual growth for Japan and a 32.8% compound annual growth rate for China (from \$2 billion in 2007 to \$8.4 billion in 2012)⁸. Much of the decline in U.S. investment came from the private sector, where its share of global R&D expenditure declined from 50.4% in 2007 to 42.3% in 2012.

This trend is very troubling indeed and potentially damaging, threatening our status as global leader. Certainty in sustained or increased federal investment in R&D is important and will help contribute to US leadership, but government policies must also provide incentives and facilitate strategic and robust investment from the private sector. A permanent R&D tax credit will not only create jobs but will create billions of dollars in additional R&D investment. Making it permanent will also promote certainty for businesses.

c. Congress Should Ensure Coordination Among Key Federal Agencies

TIA also urges Congress to work to ensure coordination across all governmental entities in providing certainty to those in the healthcare space, from the healthcare provider to the vendors that enable care. Several examples:

- We encourage CMS, the Department of Veterans Affairs (VA), and other agencies to work with the FCC on how best to position the latter's rural health connectivity programs under the Connect America Fund to holistically address the lack of availability of Internet access and communications barriers, the benefits of telehealth and remote patient monitoring, and reimbursement issues. The FCC's mHealth Task Force has already recommended in September 2012 that FCC, ONC, and CMS should seek a closer collaboration related to ongoing health IT and information exchange efforts.⁹ In a

⁸ See Chakma, et al, "Asia's Ascent—Global Trends in Biomedical R&D Expenditures." *New England Journal of Medicine* 370.1 (2014), DOI: 10.1056/NEJMp1311068

⁹ See <http://www.fcc.gov/document/fact-sheet-mhealth-task-force-recommendations>

coordinated way, CMS and VA (among others) should promote mobile broadband connectivity in rural areas and specifically address barriers to healthcare by providing HIT mobile infrastructure. Investment in multi-purpose commercial mobile broadband networks should be leveraged to support health related mobile broadband products, applications and services. Patients, doctors, and hospitals all need access to ubiquitous mobile broadband coverage if wireless health is to deliver on its potential.

- The FCC and Food and Drug Administration (FDA) should continue to build upon their 2010 Memorandum of Understanding,¹⁰ working towards innovation in broadband and wireless-enabled medical devices, and reduction of uncertainty to improve healthcare. For example, as TIA explained in its comments to the FDA on “home use” devices, the FDA should rely on the FCC for the management of harmful interference.¹¹
- The National Institute of Standards and Technology (NIST) has released guidance procedures for design evaluation and human user performance testing of EHR systems for Meaningful Use under the HITECH Act.¹² NIST’s *Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records (NIST Interagency Report 7804)* includes general steps and guidance for evaluating an EHR user interface from clinical and human factors perspectives and for conducting usability tests of an EHR user interface with representative user groups, and provides a three-step testing protocol. Separately, the Department of Health and Human Services’ Office of the National Coordinator for Health Information Technology (ONC) has issued its proposed next edition of EHR technology certification criteria for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) may voluntarily meet in order to qualify for Medicare and/or Medicaid EHR incentive payments.¹³ We believe that efforts such as this should benefit from close coordination to ensure that the guidance provided to vendors is as accurate as possible.

¹⁰ See https://apps.fcc.gov/edocs_public/attachmatch/DOC-300200A1.pdf.

¹¹ See <http://bit.ly/1kTlwCe>.

¹² See NIST, *Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records (NIST Interagency Report 7804)* (Mar. 20, 2012), available at http://www.nist.gov/healthcare/usability/upload/EUP_WERB_Version_2_23_12-Final-2.pdf.

¹³ *Voluntary 2015 Edition Electronic Health Record Certification Criteria; Interoperability Updates and Regulatory Improvements; Proposed Rule*, Department of Health and Human Services, 45 CFR Part 170 (Feb. 26, 2014).



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II. Conclusion

Telehealth and remote patient monitoring continue to change the way that health care is delivered and consumed. As we continue looking forward, it is imperative that we have policies and practices in place that enable the development of this important industry. We must continue to harness 21st century advances in science and technology, including innovative communications technologies, to ensure that Americans reap the benefits of a modern health care system.

Thank you again for your leadership, and we look forward to working with you on these important issues. For more information, please contact Danielle Coffey at (703)-907-7734 or by email at dcoffey@tiaonline.org.

Sincerely,

A handwritten signature in black ink, which appears to read 'Grant E. Seiffert'. The signature is fluid and cursive, with the first and last names being more prominent.

Grant Seiffert
President