I. Introduction

The Telecommunications Industry Association (TIA) hereby submits comments in response to the white paper “21st Century Cures: Digital Health Care.”

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 thank the Energy & Commerce Committee for this opportunity to comment.

Advances in technology have drastically changed the way healthcare is delivered and consumed, connecting patients, health care providers, and medical professionals virtually anywhere, to help facilitate ongoing care and treatment wherever and whenever it is needed. In order to realize the full potential of 21st century health care, we must have in place effective policies that promote ongoing investment and innovation to development these transformative technologies, and a regulatory framework that provides clarity and predictability instead of barriers that stifle progress.

II. 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. However, outdated regulations that have restricted the use of telehealth have long been a hindrance to progress in this space.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

Remote patient monitoring of patient-generated health data (PGHD) must be utilized for any health care system to realize its full potential. The known benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the 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 Involving this data will engage patients in their own care, can lead to improved lifestyle choices and improve overall health.⁴ 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.⁵

We urge Congress to allow for the full range of available technologies to improve quality, safety, efficiency, and reduce health disparities by engaging patients and families while improving care coordination, population and public healthcare. Policies must be in place that enable greater use of these dynamic solutions and promote greater development and opportunities for health care delivery. 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.

Another important aspect to consider PGHD is with relation to the Centers for Medicare and Medicaid Services, EHR Incentive Payment Program that oversees the “Meaningful Use” (MU)

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requirements. One of the primary goals for the program is to engage patients and their families in healthcare. However, the ability to upload PGHD that is captured by a patient’s home use or mobile medical device is not currently a part of MU, nor has this topic been adequately addressed in Stage 1 or Stage 2 of the program. TIA has long urged CMS that MU criteria should adequately account for all aspects of health IT and the full range of innovative health and medical products, such as health IT medical remote monitoring technologies that could further CMS’ goals under Meaningful Use. These technologies can provide timely and crucial information and should be part of the EHR and 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 (CCM) should be widely updated to contemplate telehealth and remote monitoring as an eligible service. In a filing to CMS in late 2013, 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. We also do not believe that CCM codes should be available only to those eligible providers (EP) who currently have met requirements under the MU program, as that would alienate other EPs who stand to benefit from these important reimbursements.

III. Regulatory Framework that is flexible and provides clarity/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.7 In a 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,8 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.9


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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.11 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.

IV. Ensuring that CMS’ Physician Fee Schedule Enables the Use of Advanced Digital Health Solutions

Recently, CMS released its proposed revisions to payment policies under the Physician Fee Schedule (PFS) for calendar year 2015.12 Notably, this proposal contains a new code for non-face-to-face chronic care management (CCM).

TIA believes that this proposal is consistent with the widely-held view that enhanced telemedicine and other related applications, including the remote monitoring of patient-generated health data (patient bio-metric data,) which have demonstrated better quality health care for patients, better access to medical specialists, and lower health care costs.13 We strongly urge Congress to confirm with CMS, for the benefit of stakeholders across the healthcare space, that its new proposed CCM code may be billed by providers to cover clinician time spent reviewing patient generated health data, i.e. patient physiological or biometric data generated from monitoring devices (a.k.a remote patient monitoring,) and not only asynchronous non-face-to-face consultation methods.


13 For example, the American Telemedicine Association offers numerous case studies that demonstrate the value of telemedicine. See http://www.americantelemed.org/learn/telemedicine-case-studies.
V. Conclusion

Telehealth continues 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 and encouraging innovation and investment into new technologies that will improve care, reduce hospital visits, and save lives.