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By Electronic Delivery

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Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0044-P
P.O. Box 8013
Baltimore, MD 21244-8013

**Re: *Medicare and Medicaid Programs; Electronic Health Record
Incentive Program--Stage 2 [CMS-0044-P]***

I. INTRODUCTION AND SUMMARY

The Telecommunications Industry Association (“TIA”) hereby submits its comments to the Department of Health and Human Services’ (“HHS”) Centers for Medicare & Medicaid Services (“CMS”) on the February 25, 2012-published proposed rules specifying the Stage 2 criteria that eligible professionals (“EPs”), eligible hospitals, and critical access hospitals (“CAHs”) must meet in order to qualify for Medicare and/or Medicaid electronic health record (“EHR”) incentive payments, along with other changes.¹ We submit these comments on the Proposed Rules to (1) urge CMS to exercise maximum flexibility in its implementation the HITECH Act, (2) to ensure that Program policies reflect the critical characteristics of technology- and competitive-neutrality, and (3) that CMS not supplant the efforts of other HHS offices administering privacy- and security-related portions of the HITECH Act.

TIA is and has been a standards development organization (“SDO”) since its inception in 1988, and is one of the largest SDOs accredited by ANSI. TIA’s standards committees create consensus-based voluntary standards for numerous facets of the ICT industry, for use by both private sector interests and government, which are directly

¹ *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2*, Department of Health and Human Services Centers for Medicare & Medicaid Services, 77 Fed. Reg. 13698-13829 (March 7, 2012) (“Proposed Rules”).

affected by the Proposed Rules.² Among other areas, TIA’s standards committees develop protocols and interface standards relating to current U.S. Government technology priorities in such areas as fiber optics, public and private interworking, telecommunications cable infrastructure, wireless and mobile communications, multimedia and voice over internet protocol (“VoIP”) access. TIA’s standards reach into areas such as Smart Grid,³ emergency communications infrastructure,⁴ and – of particular relevance to the RFI – health care ICT.⁵ TIA’s hundreds of member companies provide, develop, manufacture, and supply information and communications technology (ICT) products and services, including components of EHR systems eligible for reimbursement under the Medicare and Medicaid EHR Incentive Programs (“Programs”) under the Health Information Technology for Economic and Clinical Health (“HITECH”) Act, enacted as part of the American Recovery and Reinvestment Act of 2009.⁶ TIA members occupy critical roles in the mHealth community, producing many of the mobile devices which have become increasingly powerful tools for meeting key meaningful use objectives.

² TIA publishes an annual report that includes the latest actions taken by each respective TIA engineering committee toward the development of standards for the advancement of global communications. See TIA, Standards & Technology Annual Report (September 2010), available at http://tiaonline.org/standards/about/documents/StarReport_09-10.pdf.

³ TIA’s TR-50 (Smart Device Communications) is responsible for the development and maintenance of access agnostic interface standards for the monitoring and bi-directional communication of events and information between smart devices and other devices, applications or networks. See <http://tr50.tiaonline.org>.

⁴ Engineering Committee TR-8 formulates and maintains standards for private radio communications systems and equipment for both voice and data applications. TR-8 addresses all technical matters for systems and services, including definitions, interoperability, compatibility, and compliance requirements. The types of systems addressed by these standards include business and industrial dispatch applications, as well as public safety (such as police, ambulance and firefighting) applications. See <http://tr8.tiaonline.org>.

⁵ TIA’s TR-49 (Healthcare ICT) is responsible for development and maintenance of standards for the healthcare ICT applications which involve medical devices, network infrastructure, applications, and operations support. See <http://tr49.tiaonline.org>.

⁶ Pub. L. No. 111-5 (2009), at § 13000 *et seq.* (“HITECH Act”)

II. DISCUSSION

a. *TIA Urges Flexible and Practical Implementation of the Programs*

Initially, we urge CMS to fully appreciate the health information technology (“HIT”) ecosystem which is comprised of many technologies, including medical remote monitoring products that are enabled with information and communications technologies (“ICT”), namely wired, wireless or mobile. HIT includes the technologies that touch patients and electronically capture their physiological information and generate valuable data about the person’s health. HIT is not solely EHR’s and EHR systems, but also includes mHealth, e-Care, telemedicine⁷ and eHealth.⁸

Nationwide, hospitals are working to implement EHRs in order to advance patient care. Meaningful Use payments that fund these deployments are absolutely critical to realizing the care transformation objectives of health reform. Vendors of equipment used to implement EHR typically partner with EHR system providers, and are very receptive to the needs defined by the Program participants, and are directly affected by the Meaningful Use Stage 2 rules proposed by CMS in this matter.

TIA urges the CMS to structure its Stage 2 criteria in ways that maximize flexibility, both with respect to the types of applicants and projects eligible for support and with regard to the types of equipment and systems that may be relied upon by health-care providers. Unduly restrictive eligibility criteria would be likely to prevent funding for compelling uses that could well improve health-care service in underserved areas, substituting the Commission’s own preferences for those of individuals on the front lines of health-care delivery. The most flexible criteria will permit evaluation of individual

⁷ See Federal Communications Commission, Omnibus Broadband Initiative, *Connecting America: The National Broadband Plan*, GN Docket No. 09-51 (2010) at p. 218 (providing definitions of “health IT,” “mHealth,” “e-Care” and “Telehealth”), available at <http://download.broadband.gov/plan/national-broadband-plan.pdf>.

⁸ See CMS, E-Health General Information, <https://www.cms.gov/Medicare/E-Health/EHealthGenInfo/index.html?redirect=/EHealthGenInfo/> (last visited May 4, 2012) (defining “eHealth”).

applications on their merits, in ways that account for the specific applicant's needs, not to mention its belief that the project would be worthwhile and its willingness to invest additional funds. In some instances, we believe that CMS exhibits such an understanding. In TIA's view, this approach is consistent with President Obama's recent Executive Order calling on federal agencies to "reassess and streamline regulations" to reduce barriers to investment and innovation.⁹

For example, based on CMS' statement that 8 percent of hospitals and 4 percent of physicians attested to meaningful use and received Medicare EHR incentive payments in the first year of the program,¹⁰ TIA supports the CMS proposal to delay the onset of Stage 2 criteria until 2014 to allow for more time for vendors to develop Certified EHR Technology.¹¹ Decisions that reflect practical realities will help make the program as inclusive as possible and push towards realizing the HITECH Act. Significantly raising standards for Stage 2 criteria could widen the gap in eligibility that exists between larger hospitals and small, remote hospitals, emphasizing the need for flexible rules and evaluations in CMS' administration of the Programs.

We believe that the manner in which CMS evaluates and administers EP hardship exceptions will be crucial to the success of the Programs.¹² We strongly urge CMS expand on its willingness to waive criteria when circumstances warrant in order to provide increased certainty to Program participants, and to ensure that the program is as inclusive as possible. Only a public commitment to such waivers can ensure that worthy applicants are not deterred by requirements that would bar their proposed projects, but that could be waived.

⁹ See Presidential Memorandum: Regulation and Independent Regulatory Agencies (Jul. 11, 2011), available at <http://www.whitehouse.gov/the-press-office/2011/07/11/memorandumregulation-and-independent-regulatory-agencies>.

¹⁰ See Proposed Rules at 13801.

¹¹ *Id.* at 13701.

¹² *Id.* at 13769-13772.

The Proposed Rules contain discussion on other possible exceptions, and note that (i) lack of direct interaction with patients, (ii) lack of need for follow-up care for patients, and (iii) lack of control over the availability of Certified EHR Technology can constitute a significant hardship for EPs.¹³ Contrary to the belief of CMS,¹⁴ TIA believes that any one of these three barriers could indeed alone constitute a sufficient basis for eligibility under a hardship exemption, particularly the lack of availability of Certified EHR Technology. In addition, there will certainly exist circumstances where all three barriers will be faced by a particular specialty. We believe that a flexible, case-by-case determination which does not institute such heavy-handed policies as requiring more than one of the suggested barriers would keep the Programs as inclusive as possible and maximize their reach.

b. *Ensuring Fair Treatment of Program Participants and Technologies to Fully Realize the Benefits of the Programs*

We believe that CMS should make all reasonable efforts to ensure that all eligible participants – from large, urban hospitals to the smaller rural facilities – are given an equitable opportunity to realize the benefits of the programs. Aside from the flexibility in implementation of the rules that TIA advocates above, we urge CMS to ensure that it takes an approach that is ever-mindful of principles of technology- and competitive-neutrality. TIA is a long-time advocate for policies that promote technology- and competitive-neutrality, in which standards and products are developed by market-driven dynamics and open, transparent processes. As CMS moves forward in setting goals for the Programs, it should build upon the belief that technology neutral policies are critical in promoting competition and ensuring that Program participants are empowered to choose technologies that best suit their needs.

¹³ Proposed Rules a5 13770-13771.

¹⁴ *Id.* at 13771.

TIA also notes its long-standing concern¹⁵ with the CMS rules which treat all facilities operating under the same health care provider as a single entity, and require compliance on a system-wide basis (i.e., for all entities sharing a Centers for Medicare and Medicaid Services provider number).¹⁶ As we have previously noted to the Federal Communications Commission's ("FCC") in response to their proposal to, "assuming full implementation of meaningful use requirements in 2015, [require] recipients of funding from the Rural Health Care Support Mechanism...to document their compliance with meaningful use requirements as a condition of receiving support"¹⁷ under the Rural Healthcare Support Mechanism (of the Universal Service Fund),¹⁸ the existing "meaningful use" rules treat all facilities operating under the same health care provider as a single entity, and require compliance on a system-wide basis. This policy could deny reimbursement funding to fully compliant hospitals or clinics merely because sister institutions were non-compliant. We strongly urge CMS to alter its rules under Stage 2 to ensure that providers are not punished by the failure of other institutions, beyond their control, to adopt electronic health record technologies.

¹⁵ See Comments of TIA to the FCC, WC Docket No. 02-60 (filed Sept. 8, 2010) at 6-10, available at http://www.tiaonline.org/gov_affairs/fcc_filings/documents/TIA_RHC_Comments_090810.pdf.

¹⁶ See, e.g., iHealthBeat, CMS Holds Steady on Multicampus Rule for "Meaningful Use" Pay (July 30, 2010), available at <http://www.ihealthbeat.org/articles/2010/7/30/cms-holds-steady-on-multicampus-rulefor-meaningful-use-pay.aspx>.

¹⁷ See *Rural Health Care Support Mechanism*, Notice of Proposed Rulemaking, WC Docket No. 02-60 (rel. July 15, 2010) at ¶ 144.

¹⁸ The Rural Health Care Program ("RHCP") created in 1997, ensures that rural health care providers pay no more than their urban counterparts for their telecommunications needs in the provision of health care services, and provides a 25 percent discount off the cost of monthly Internet access for eligible rural health care providers. See <http://www.usac.org/rhc/>. The Rural Health Care Pilot Program ("RHCPP"), created in 2006, allows eligible health care providers to receive universal service funding to support up to 85 percent of the eligible costs of broadband infrastructure deployment of telehealth networks that connect to rural and urban health care providers in a State or region. See <http://www.usac.org/rhcp/>. Both are administered by the Universal Service Administrative Company, which reviews applications, invoices, and other program information to determine if applicants and service providers follow rules for the program set by the FCC, as well as conducts Rural Health Care Program beneficiary audits to confirm program compliance.

In addition, we urge CMS 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. The proposed Stage 2 criteria do not adequately account for the full range of products, such as HIT medical remote monitoring products that could further CMS' goals under Meaningful Use State 2. Innovative technologies such as these can provide timely and crucial information to EHR systems. Further, Meaningful Use Stage 2 criteria as proposed lacks instruction on how EP's, EH's and CAH's are 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. Though Meaningful Use is seeking to engage patients and their families, yet the important information captured by a patient's home medical device is currently not contemplated to become a part of the care record.

c. *Coordination with Other Governmental Offices and Agencies in Formulating Program Policies and Implementing the Programs*

TIA urges CMS to coordinate with all other governmental entities in providing certainty to the Program participants as well as the vendors that enable compliance with Meaningful Use requirements. For example, 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.¹⁹ 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. We believe that efforts such as this should benefit from close coordination from CMS as well as the Office of the National Coordinator ("ONC") to ensure that the guidance provided to vendors is as accurate as possible.

¹⁹ 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.

Furthermore, HITECH Act implementation should be implemented in-step with other government initiatives related to proliferating EHRs, such as the FCC’s above-discussed RHCP and RHCPP.²⁰ We encourage CMS to work with the FCC on how best to position the Commission’s RHCP and RHCPP to address the lack of availability of Internet access and communications barriers. These two universal service programs 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 better informed vendors are as to the requirements each recipient under HIT-related programs, the higher the likelihood of compliance with Meaningful Use requirements, and, more broadly, the more ease the health care system will have in modernization efforts.

TIA also believes that the protections for individually identifiable health information provided for Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)²¹ are very important. The HHS Office for Civil Rights (OCR) solely enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information, as well as the HIPAA Security Rule, which sets national standards for the security of electronic protected health information. It appears that CMS’ proposal to “provide patients the ability to view online, download, and transmit information about a hospital admission” under Stage 2 Meaningful Use²² may be supplanting OCR’s role in its enforcement of the HITECH Act and HIPAA. TIA therefore believes that CMS should coordinate closely with OCR in its ongoing rulemaking activities before making any Stage 2 rules related to privacy or security.

²⁰ We believe that HHS’ engagement with the FCC in the creation of the Connect America Fund via public comment is a good start. *See, e.g.*, Comments of HHS, WCB 10-90 (filed Apr. 18, 2011).

²¹ Pub. L. No. 104-191, 110 Stat. 1936 (1996), *codified*, as amended, at 42 U.S.C.A. §1320 *et seq.*

²² Proposed Rules at 13718-13720.

III. CONCLUSION

We congratulate CMS in their efforts to implement EHRs by examining Meaningful Use Stage 2 and urge the adoption of rules consistent with the above positions. We urge CMS to contact us with any questions or concerns you may have with our positions as it considers this proposal.

Respectfully submitted,

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