December 15, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3310 & 3311-FC
P.O. Box 8013
Baltimore, MD 21244-1850

RE: **Comments of ACT | The App Association regarding the Center for Medicare &**
Medicaid Services' *Medicare and Medicaid Programs; Electronic Health Record*
Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through
2017

Dear Dr. DeSalvo:

ACT | The App Association writes to provide comments to the CMS on its final rule specifying
the criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals
(CAHs) must meet in order to qualify for Medicare and Medicaid electronic health record (EHR)
incentive payments and to avoid downward payment adjustments under the Medicare EHR
Incentive Program.[1] ACT | The App Association represents more than 5,000 app companies
and technology firms that create the apps used on smartphones around the globe. As the
world has quickly embraced mobile technology, our member companies have been creating
innovative solutions across modalities and segments of the economy, with no stronger an
example than healthcare. For example, ACT | The App Association is spearheading the
Connected Health Initiative, an effort to clarify outdated health regulations, incentivize the use
of remote patient monitoring, and ensure the environment is one in which patients and
consumers can see improvement in their health.[2] This coalition of leading mobile health
companies and key stakeholders urge Congress, the Food and Drug Administration (FDA), the
Center for Medicare & Medicaid Services (CMS), and other key policymakers to adopt policies
that encourage mobile health innovation and keep sensitive health data private and secure.

In its final rules for Meaningful Use Stage 3 (MU3) of the EHR program, CMS took a significant
step to support the interoperable exchange of health information by including application
programming interfaces (APIs) utilization within its view, download, and transmit (VDT) criteria.
We fully support CMS' decision to include this requirement, as well as related measures
regarding patient-generated health data (PGHD), and urge for their retention in MU3.

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[1] *See Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications*
to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62761 (Oct. 16, 2015) (MU3 Final Rules).

[2] "Connected Health Initiative." Available at: http://connectedhi.com.

CMS defines an API as "a set of programming protocols established for multiple purposes…[that] may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current 'patient portals.'"[3] CMS goes on to explain that "[i]f the provider elects to implement an API, the provider would only need to fully enable the API functionality, provide patients with detailed instructions on how to authenticate, and provide supplemental information on available applications which leverage the API."[4] In practice the software application developer community relies on APIs to establish interoperability in a safe and secure manner across contexts. APIs are not just technical specifications regulating how data can be exchanged on a network, but should be understood as a technique for governing the relations these networks contain.[5]

As EPs, eligible hospitals, and CAHs across the United States work to implement EHR systems in order to advance patient care, Meaningful Use payments that fund these deployments are critical to realizing the care transformation objectives of health reform. Further, patient access to their electronic health information and educational resources are critical tools that empower and engage patients in their own care, enabling more informed lifestyle and care decisions. Therefore, increased patient investment and engagement facilitated by store-and-forward technology (ranging from medical device remote monitoring products to general wellness products) that incorporates PGHD into EHRs, facilitated by APIs, is crucial to carrying out Congress' vision in the Health Information Technology for Economic and Clinical Health (HITECH) Act.[6]

Remote monitoring of PGHD is increasingly being proven as an important aspect of any healthcare system. The demonstrated benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.[7] A particularly compelling example of the use of virtual chronic care management is by the Department of Veterans Affairs, which resulted in a substantial decrease in hospital and emergency room use.[8] Telemedicine tools, wireless

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[3] 80 FR 16753.

[4] *Id.*

[5] *See* Galloway, Alexander R. Protocol: How Control Exists after Decentralization. Cambridge, Mass.: MIT Press, 2004.

[6] Pub. L. No. 111-5 (2009), at § 13000 *et seq*.

[7] *See* Hindricks, et al., The Lancet, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4. *See also* 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.

[8] Darkins, Telehealth Services in the United States Department of Veterans Affairs (VA), *available at* http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf.

communication systems, portable monitors, and cloud-based patient portals that provide access to health records are all emerging technologies that are revolutionizing remote patient monitoring (including asynchronous technologies) and the medical care industry, representing a significant opportunity.[9] There is also a growing body of potential cost savings to provides, noted most recently by a study predicting that remote monitoring will result in savings of $36 billion globally by 2018, with North America accounting for 75% of those savings.[10] RPM has the potential to positively engage patients when addressing chronic and persistent disease states to improve management of chronic conditions. Despite the benefits of including PGHD in the continuum of care being widely established, and in the face of an almost total lack of support in any form through key US Government programs or subsidies – remote monitoring of PGHD continues to represent the most promising avenue for improving care quality while lowering costs.

Coupled with EHR data stored in standardized formats with interoperability facilitated by APIs, PGHD provides the capability for analytic, as well as near real-time, alerting capabilities. The use of API's to design solutions and platforms for data streams from multiple and diverse platforms and sources (including PGHD) will directly contribute to areas of needed improvement in the healthcare sector, including information silos, data blocking, and deficient patient engagement in care.

The utilization of open and consensus-driven and voluntary standards is a long-standing Federal policy that promotes effective and efficient technology and innovation in the global marketplace.[11] In the context of Meaningful Use, open standards will be a cornerstone to interoperability, and will promote innovation in the eHealth marketplace. We note that technology, standards, and products are available today to facilitate the data exchange of patient data to a clinical EHR, including health reporting network interfaces that establish standards for exchange of patient summaries between remote monitoring systems and certified EHR technologies. These standards include: the Continua Alliance's Design Guidelines,[12] Health Level 7 (HL7),[13] ISO 12052 (Health informatics -- Digital imaging and communication in medicine including workflow and data management),[14] and the Integrating the Healthcare Enterprise (IHE) initiative.[15]

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[9] Kalorama Information, *Advanced Remote Patient Monitoring Systems*, 8th Edition (2015), *available at* http://www.kaloramainformation.com/redirect.asp?progid=87656&productid=9123949.

[10] 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.

[11] *See* OMB Circular A-119 Revised, *Federal Participation in the Development And Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (rev. Feb. 10, 1998), *available at* http://www.whitehouse.gov/omb/rewrite/circulars/a119/a119.html.

[12] http://www.continuaalliance.org/products/design-guidelines.

[13] http://www.hl7.org/implement/standards/index.cfm.

[14] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43218.

[15] http://www.ihe.net/About_IHE/.

For those who participate in the Meaningful Use program, the use of these standards for interoperability between providers, as well as between remote patient monitoring devices and EHRs, for functions will 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. Such voluntary industry standards along with consensus on specifications for interoperability between remote monitoring systems and EHRs already exist, continue to be developed and refined, and are currently available for use in systems and products. We maintain that CMS (and ONC) should tie incentive payments to the use interoperable EHR products that guarantee useable data regardless of vendor through the use of open APIs.
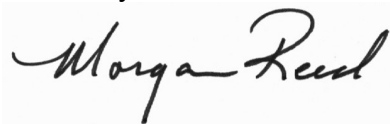
Based on the above, we support MU3 measures that facilitate the flow of PGHD through the use of open APIs, which will help ensure the ability to access and update health information through an API is a reality of patient care. We support the Options underneath this Measure as they will provide needed flexibility to eligible parties and that this flexibility will lend to improve data exchange as well as greater incorporation of PGHD into the treatment of millions of American Medicare beneficiaries. Further, the retention of such measures in MU3 will contribute to the goals of Congress in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[16] by incenting foundational deployments of health information technology that will assist in moving from a 'quantity' Medicare reimbursement system to one based on 'value,' and providing improved care to hundreds of millions of Americans, particularly those requiring chronic care management.

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[16] Pub. L. 114-10 (2014).

ACT | The App Association appreciates the opportunity to submit comments to CMS on its MU 3 rules, and look forward to the opportunity to meet with you and your team to discuss these issues in more depth. Thank you for your consideration.

Sincerely,

Morgan Reed
Executive Director
ACT | The App Association