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June 3, 2016

ATTN: RFI Regarding Assessing Interoperability for MACRA
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW, Room 7025A
Washington, District of Columbia 20201

RE: Comments of the Connected Health Initiative regarding *Medicare Access and CHIP Reauthorization Act of 2015*; Request for Information Regarding Assessing Interoperability for MACRA (HHS-ONC-2016-0008)

The Connected Health Initiative writes to provide comments to the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) in response to its Request for Information (RFI) regarding the exchange of health information through interoperable certified electronic health record (EHR) technology nationwide.¹

The Connected Health Initiative, convened by ACT | The App Association, represents the leading effort by connected health ecosystem stakeholders to effort to clarify outdated health regulations, incentivize the use of remote patient monitoring (RPM), and ensure the environment is one in which patients and consumers can see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 urges Congress, ONC, the Food and Drug Administration (FDA), the Center for Medicare & Medicaid Services (CMS), and other policymakers to adopt frameworks that encourage mobile health innovation and keep sensitive health data private and secure.

¹ *Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015; Request for Information Regarding Assessing Interoperability for MACRA*, 81 Fed. Reg. 20651 (Apr. 8, 2016).

² "Connected Health Initiative," available at <http://connectedhi.com>.

I. Interoperable Exchange of Health Information throughout the Continuum of Care

ONC's determination of the extent of widespread exchange of health information comes at an important time. First, ONC's evaluation and related recommendations to Congress provide an opportunity to improve on the approach taken in the Meaningful Use incentive payment program. Further, electronic health information and educational resources are critical tools that empower and engage patients in their own care. A truly interoperable eCare system includes patient engagement facilitated by store-and-forward technologies (ranging from medical device remote monitoring products to general wellness products) with open application interfaces (APIs)³ that allow the upload of patient-generated health data (PGHD) into EHRs. Data stored in standardized formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms for data streams from multiple and diverse sources will improve the healthcare sector, helping to eliminate information silos, data blocking, and deficient patient engagement.

Interoperability must not only happen between providers, but also between RPM products, medical devices, and EHRs. A great example of interoperable systems, devices, and networks is the communications technology industry which has flourished globally through ubiquity. Voluntary industry standards along with consensus on standards (and testing to such standards) for interoperability between EHR systems and medical devices and healthcare products should become a priority for ONC. It is crucial that ONC reflect this in its approach to measuring the interoperability of EHR products. A system demonstrating "widespread interoperability" will provide useable data from various sources, not only certified EHR technology (CEHRT) and CEHRT systems (regardless of vendor and products). Even with the best standards in place, there needs to be an incentive to communicate, passing information from one party to another. The Medicare Access and CHIP Reauthorization Act⁴ (MACRA) provides that incentive in a value-based environment of health care, one which engages patients, reduces costs, and documents quality metrics.

³ 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.'" 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." See 80 FR 16753. 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.

⁴ Pub. L. 114-10 (2015).

Remote monitoring of PGHD is a proven necessity for the future of the American healthcare system. The demonstrated benefits of RPM services include improved care, reduced hospitalizations, reduced cost, avoidance of complications, and improved stakeholder satisfaction, particularly for the chronically ill.⁵ A compelling example of the use of virtual chronic care management comes from the Department of Veterans Affairs, which resulted in a substantial decrease in hospital and emergency room use.⁶ Emerging technologies like telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are revolutionizing RPM, including asynchronous technologies.⁷ Providers will also benefit from a growing body of potential cost savings, 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 percent of those savings.⁸ RPM has the potential to positively engage patients when addressing chronic and persistent disease states to improve management of such conditions.

In recognition of the promise of PGHD, ONC announced that it will develop a policy framework for identifying best practices, gaps, and opportunities for the use of PGHD in research and care delivery through 2024.⁹ We support this effort within ONC, and encourage ONC to develop its efforts under MACRA as remote monitoring of PGHD continues to represent the most promising avenue for improving care quality while lowering costs.

II. ONC Should Reflect the Connected Continuum of Care in the Scope of its Evaluation Under Section 106(b)(1)

⁵ 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>.

⁶ 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>.

⁷ The global wearable medical devices market is expected to progress from US\$2.73 bn in 2014 to US\$10.7 bn by 2023, predicted to progress at a 16.40% CAGR from 2015 to 2023. See <http://www.medgadget.com/2016/05/global-wearable-medical-devices-market-to-reach-us10-7-bn-by-2023-as-increasing-incidence-of-chronic-pain-creates-strong-customer-base.html>.

⁸ 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.

⁹ <https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data>.

In the RFI, ONC discusses the appropriate scope of measurement for its activities pursuant to 106(b)(1) of MACRA and raises a number of related questions. We share ONC's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD, consistent with the Interoperability Roadmap and MACRA.

In the "learning health system enabled by nationwide interoperability" envisioned in the Interoperability Roadmap, ONC details the components of the future interoperable roadmap which include data generated by patients outside of the traditional care setting. For example, ONC states that "[a]ccess to seamless and secure patient data across the care continuum will be an expectation for providers serving the beneficiaries of federal health plans,"¹⁰ where "[i]ndividuals are able to seamlessly integrate and compile longitudinal electronic health information across online tools, mobile platforms and devices to participate in shared decision-making with their care, support and service terms."¹¹ The scope chosen by ONC should build on and incorporate ONC's vision in both its Interoperability Roadmap as well as its ongoing PGHD framework development PGHD's promise.

A scope that includes PGHD would also be consistent with the direction of HHS health technology policy. In its final rules for Meaningful Use Stage 3 (MU3) of the EHR program, CMS already took steps to support the interoperable exchange of health information by including API utilization within its view, download, and transmit (VDT) criteria, as well as related measures regarding PGHD. We urge both ONC and CMS, in the MACRA Advancing Care Information (ACI) program measures, to ensure that companies providing connected health solutions are not incented to limit the innovative features of their products and services due to overly-prescriptive ACI requirements, as well as that the measures used provide flexibility for physicians and other clinicians to select the most effective approaches for their patients. This will require both ONC and CMS to work closely with the stakeholder community to ensure that the ACI measures capture interoperability across the continuum of care as described above, which is best approached through outcome-based measures that are agnostic to the processes used to meet those goals.

Further, a broader scope would also be consistent with the aims of MACRA's Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs), about which ONC specifically raises a question in the RFI.¹² For example, MACRA lists six subcategories of clinical practice improvement activities that contribute to the MIPS composite score, one of which is care coordination, specifically "including use of remote monitoring or

¹⁰ Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap at 53.

¹¹ *Id.* at 73.

¹² RFI at 20653.

telehealth.”¹³ ONC would therefore be remiss in adopting a scope that would not contemplate the important PGHD deriving from telehealth and remote monitoring. Finally, the broader scope we suggest should also be consistent with ONC’s policy framework for identifying best practices, gaps, and opportunities for the use of PGHD in research and care delivery through 2024, currently under development.

ONC also requests input on defining “widespread interoperability” in the RFI.¹⁴ Consistent with the above, “widespread interoperability” should be defined to necessarily include the incorporation of PGHD through certified EHR technology.

III. ONC Should Fully Leverage Data Sources to Evaluate Interoperability

In the RFI, ONC discusses in detail the potential data sources it may utilize in its evaluation activities under section 106(b)(1).¹⁵ While we believe that ONC should certainly utilize data streams that it currently employs and which are available today (such as measures from CMS EHR Incentive Programs), it is important for ONC to recognize that these metrics alone are insufficient to measure interoperability. Existing metrics for the MU program focus on the “quantity” of exchange as opposed to the “quality.” Consistent with our discussion above, CHI believes that appropriately employing algorithms on data of sufficient quality can provide numerous opportunities for capturing both the quality and (more importantly) interoperability of healthcare data. Therefore, we support the ONC suggestion to use surveys of hospitals conducted with the American Hospital Association. We further support the use interoperability use cases and clinician experience surveys that capture the goals of the MU program (and ACI program) rather than quantity-based measures which have spurious connections to evaluating interoperability. While patient access to data is important, clinicians also need interoperable data from a variety of sources to integrate seamlessly into their work flow. Third party applications will play a major role in satisfying this need to ensure data “quality” so that physicians get the most relevant data in a useable format, when and where they need it.

¹³ MACRA Section 101(c)(2)(B)(iii)(III).

¹⁴ RFI at 20655.

¹⁵ RFI at 20653.

We appreciate the opportunity to submit comments to ONC on this matter 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,

A handwritten signature in black ink that reads "Morgan Reed". The signature is written in a cursive style with a large, prominent 'M' and 'R'.

Morgan Reed

Acting Director
Connected Health Initiative

Executive Director
ACT | The App Association