



Office of the National Coordinator for Health Information Technology  
Attention: HITECH Initial Set Interim Final Rule  
Hubert H. Humphrey Building  
Suite 729D  
200 Independence Ave., SW.  
Washington, DC 20201

RE: RIN 0991–AB58

Dear Dr. Blumenthal:

The more than 230 members of the Continua Health Alliance (Continua) commend the Office of the National Coordinator for Health Information Technology (ONC) for accepting comments related to its Interim Final Rule on initial standards, implementation specifications and certification criteria (Interim Final Rule). Continua is a non-profit, open industry coalition of healthcare, technology and medical device companies joining together in collaboration to improve the quality of healthcare through the use of personal connected health, remote patient monitoring (RPM) and other health information technologies. Continua is dedicated to establishing interoperable personal health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals and provides the opportunity for personalized health and wellness. More information about Continua and its members can be found at [www.continuaalliance.org](http://www.continuaalliance.org).

Continua appreciates the ONC’s commitment to setting forth standards that will “support the achievement of the proposed meaningful use Stage 1 (beginning in 2011) by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive



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Programs.”<sup>1</sup> We understand how this Interim Final Rule works in tandem with the current Notice of Proposed Rulemaking on the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program (Proposed Rule) recently issued by the Centers for Medicare and Medicaid Services (CMS), and Continua will also be submitting comments on that Proposed Rule.

As a policy matter, Continua believes it is important for CMS and the ONC to recognize the importance of ensuring the continuum of care for patients. The Proposed Rule and Interim Final Rule will encourage the adoption of EHRs and steer the direction of their use. However, if the ultimate goal of EHR use is to increase the quality, efficiency and safety of the healthcare system, then the entire ecosystem of HIT must be considered in order to reach that goal. Health information technology (HIT), including RPM, telehealth, and mobile health (mHealth) (collectively referred to as “eCare”), ensures timely and adequate healthcare for the frail, the elderly, those living in rural and underserved areas, and patients who need continuous remote monitoring following hospital discharge.

We appreciate that CMS is gradually expanding the goals of HIT use through its proposed implementation of three phases of meaningful use. However, in the HIT Policy Committee’s final recommendation to CMS, Continua was disappointed to see that the incorporation of data from home monitoring devices and medical device interoperability were not included as objectives until Stages 2 and 3 respectively. While we understand that under the current proposal RPM technologies may take on a more important role in later stages of meaningful use, Continua believes it is extremely important to ensure that the initial stage of the definition and the associated standards, implementation specifications and certification criteria do not stifle current adoption or confuse providers currently using these health information technologies to discontinue their use.

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<sup>1</sup> Office of the National Coordinator for Health Information Technology, Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 8, 2014 (January 13, 2010).

As health information technologies like remote patient monitors, telehealth devices and mobile health (mHealth) continue their rapid evolution and increasingly become the focus for the provision of healthcare, it will be those wired, wireless and mobile devices, sensors, products, and applications that will derive and capture health information data for applicable facets within the HIT ecosystem including helping to populate EHRs. Although Continua is in full support of the ONC’s decision to allow eligible professionals (EPs) and hospitals to use a combination of EHR modules in order to achieve meaningful use, we want to ensure that health information technologies, such as interoperable RPM devices, can be certified as EHR modules. We believe these devices should fall under the definition of EHR module “EHR Module to mean any service, component, or combination thereof that can meet the requirements of at least one certification criterion” and definitional category of “an interface or other software program that provides the capability to exchange electronic health information.”<sup>2</sup> RPM devices can directly populate a patient’s EHR whether the device is used in the professional’s office or the patient’s home. Data from RPM devices is essential for timely care as these devices supply trending data that can assist physicians, nurses and other healthcare professionals in collecting unique patient health information and data. The data collected by these devices provides the necessary elements for cost-effective, timely treatment, which helps avoid costly hospitalizations or readmissions. Services provided through interoperable RPM devices extend an EP’s reach and should be viewed as an extension of the services offered in the professional’s office.

In general, Continua also suggests that the ONC consider an alternative understanding of “interoperability.” While we agree “that certification should focus on meaningful use and be leveraged to improve security, privacy, and interoperability”<sup>3</sup>, ultimately, the goals of expanding HIT use will be met by encouraging broad adoption. Interoperability is the

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<sup>2</sup> *Id.* at 2022.

<sup>3</sup> *Id.* at 2024.



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key to ensuring this information can be leveraged to produce higher quality care and better outcomes. With the current shortage of physicians and the increased need for timely patient data, it would be shortsighted not to view the use of RPM devices as a logical extension of the meaningful use of EHRs. Thus, Continua believes the ONC should explicitly specify that RPM devices which are capable of capturing data are included in the Stage 1 definition of meaningful use, in addition to allowing RPM devices to be certified as EHR modules thereby qualifying EPs for incentive payments. This will ensure the foundation for the use and certification of these technologies under the meaningful use definition and as the standards implementation specifications and certification criteria evolve in future years.

Continua is appreciative of this opportunity to comment on the Interim Final Rule and commends the ONC's development of the first iteration of standards, implementation specifications and certification criteria. We believe HIT enabled by powerful wired, wireless and mobile broadband networks currently exists and is available today to supplement America's healthcare delivery. HIT, when used as part of an interoperable ecosystem, will advance our healthcare needs and lead to improved quality and health outcomes. We have extensive experience in the development and use of RPM devices, telehealth, and mHealth, which can enhance the delivery of care and extend oversight of patients beyond the physician's office. If we can be of any further assistance to the ONC as the Interim Final Rule is finalized, we would be eager to share our experiences and knowledge.

Sincerely,

Charles Parker

Executive Director

Continua Health Alliance