

May 2, 2016



Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health IT
Office of the National Coordinator
Hubert H. Humphrey Building Suite 729 D
200 Independence Ave, S.W.
Washington, DC 20201

311 Arsenal Street
Watertown, MA 02472

Re: ONC Health IT Certification Program: Enhanced Oversight and Accountability

Submitted electronically via www.healthit.gov

Dear Dr. DeSalvo,

athenahealth Inc. (athenahealth) appreciates the opportunity to comment on the Office of the National Coordinator's (ONC) Health IT Certification Program: Enhanced Oversight and Accountability proposal.

As you know, athenahealth provides electronic health records (EHR), practice management, care coordination, patient communication, data analytics, and related services to physician practices and hospitals, working with a network of over 78,000 healthcare professionals in all 50 states. All of our providers access our services—and over 38 million active patient records—on the same instance of continuously-updated, cloud-based Certified Electronic Health Record Technology (CEHRT). Our clients' successes, exemplified by a Meaningful Use (MU) attestation rate more than double the national average, underscore the very real potential of data and health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

We strongly oppose ONC's proposal to augment its regulatory authority over health IT products at a time when efforts should be exclusively focused on reducing the burdensome elements that already plague the certification program. The authority laid out in this proposal is far beyond the scope that Congress envisioned when it established a certification program and it paves the way for future land grabs that will inhibit the entire industry. Under the auspices of public safety, ONC's proposal simply sets the table for capricious application of oversight authority that is likely to further burden health IT while stifling ingenuity and progress.

Although there are clear and compelling reasons to take aim at reducing red tape, the proposal will instead further increase the administrative burden and cost associated with certification for both health IT developers and government bodies alike. The current certification program requires a significant investment of time and resources

from highly skilled developers whom ONC annually forces to demonstrate painstaking compliance with trivial functionality, which the majority of health IT developers have regularly shown is well within their capabilities. This attention given to basic compliance on a recurring basis reduces the resources that health IT developers can devote to responding directly to consumer (physician) needs. Program add-ons, such as this increased oversight, neither address the challenges of ingenuity-crippling certification protocols today nor improve the program or health IT products.

In light of the fact that ONC has demonstrated a preference for relying on burdensome and out-of-touch regulations when it acted within the sphere that Congress established for it, the most concerning aspect of the proposal is the limitless scope ONC grants itself to review the entire health IT product, including components well beyond certification requirements. A complaint directed towards a CEHRT, or ONC's own initiative, should not make it within ONC's authority to investigate non-certifiable components of CEHRT and dictate how a company builds and modifies a product in response to market mandates. The proposal's broad authority for ONC to investigate and act on potentially unsubstantiated, malicious or subjective reports, such as usability, will be detrimental to the organic innovation necessary for successful and forward thinking development of health IT products that solve the problems of many, but not necessarily every individual.

In closing, we disagree with ONC's efforts to regulate outside its proper scope. We strongly oppose the nature of this proposal due to the excessive reach ONC seeks well beyond what is needed to accomplish what Congress intended when it conceived of a certification protocol.

Sincerely,

A handwritten signature in black ink, appearing to read "Greg Carey", is placed over a white rectangular background.

Greg Carey
Technology Standards & Policy Manager
athenahealth, Inc.