April 24, 2014

Dr. Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria;
Interoperability Updates and Regulatory Improvements proposed rule

Dear Dr. DeSalvo:

On behalf of the American Academy of Family Physicians (AAFP), which represents
110,600 family physicians and medical students across the country, I write in response to
the "Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria;
Interoperability Updates and Regulatory Improvements" proposed rule as published in the
March 19, 2014, *Federal Register*.

This proposed rule initiates the Office of National Coordinator for Health Information
Technology's (ONC's) "more frequent approach to health information technology certification
regulations." The proposed rule discusses ONC's intent to update certification criteria
editions every 12 to 18 months in order to provide smaller, more incremental regulatory
changes and policy proposals and that the agency wants to provide "greater and earlier
visibility to our regulatory direction before compliance is required." ONC then outlines 2015
edition EHR certification criteria as voluntary and discusses how EHR technology
developers who certified as EHR technology to the 2014 Edition would not need to recertify
to the 2015 Edition in order for its customers to participate in the Medicare and Medicaid
EHR Incentive Programs.

The AAFP appreciates that ONC is attempting to establish a process for more frequent,
visible and incremental changes to EHR certification criteria. Providing EHR developers with
advanced notification of future mandatory certification criteria is useful for developers and
physicians alike as it provides all stakeholders with time to prepare and test software
upgrades before the standards are mandatory and associated with punitive financial
penalties for noncompliance. The AAFP supports steps ONC can take that provide more
lead time for software development since this helps AAFP members' interactions with
vendors struggling to comply with Meaningful Use timelines and requirements.

However, the AAFP also is concerned that the proposed rule creates potential confusion for family physicians over what level of certification is actually required for their EHR to qualify to attest to Meaningful Use. The proposed approach also allows vendors to potentially market and sell an update as required when it is not. The 2015 voluntary edition might be seen as a forecast of future requirements for the next mandatory certification, yet that is not guaranteed by ONC, which further concerns the AAFP.

The Meaningful Use program continues to be a complex program and the AAFP works to help our members successfully navigate the program. The AAFP urges ONC not to add another layer of complexity to this program by creating a new and voluntary certification level. We appreciate efforts by ONC to promptly notify stakeholders with future mandatory reporting, yet we urge ONC to work with stakeholders to create better means than a voluntary certification program.

In regards to discontinuing "complete EHR" certification, the AAFP supports the discontinuation of this type of designation. The AAFP is concerned that physicians must purchase add-on products from vendors solely when a vendor certified as only a complete EHR. Should the physician wish to use another "module" from another vendor, it would then force the practice to purchase the "module functionality" from both vendors. Instead, the AAFP recommends that each product being certified contain a listing of all Meaningful Use certification criteria and an indication of "passed," "failed" or "not tested" for each criterion.

In regards to recommended testing changes, we agree with the proposal of separation of content from transport testing. This may have several benefits to AAFP members using EHRs. It will simplify the EHR certification process from a content generation and consumption perspective, thereby better assuring standard practices for use of the Consolidated Clinical Document Architecture (CCDA) and possibly other payloads. Transport requirements may change over time without affecting content requirements, so de-coupling these is a more efficient approach. Further, our involvement with DirectTrust's interoperability testing leads us to conclude that additional strengthening of ONC and National Institute of Standards and Technology (NIST) testing conditions for Health Information Service Provider (HISP) to HISP transport is very much needed to avoid "downstream" failures of Direct exchange among EHR using eligible providers and hospitals. Separation of the testing of Direct protocol for transport should allow ONC and NIST to give the market better EHR products and modules more capable of smooth interoperability.

The AAFP also agrees with recommended changes that would allow EHRs and HISPs to separately certify their products, so that an EHR technology would become "Direct Ready" versus "Direct Enabled." This would allow EHR users to avoid being "locked in" to the choice of HISP made by their EHR vendor, and give those providers and hospitals additional choice by making the relationship between core EHR and Direct transport module (provided by the HISP) a true plug-and-play situation. Specifically, the proposed rule along with the utilization of the Implementation Guide for Edge Protocols would require an EHR to support a customer's decision to change to a new HISP vendor should the EHR's own solution for Direct services not meet the practice's requirements. However, the AAFP advises ONC to give the EHR vendors who may have tightly coupled Direct provider solutions time to make the necessary changes to their edge protocols, and the AAFP would advise ONC to be very clear about which edge protocols are required, and those considered optional, for both parties, the EHR technologies and the HISPs.

Finally, the AAFP urges ONC to improve the current tool to assist eligible professionals in determining what products are certified. The usability of the website continues to be a challenge for our members. The AAFP is available to meet with ONC staff to provide further recommendations on much needed improvements.

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have. Please contact Steven E. Waldren, MD MS, Senior Strategist for Health Care IT at 1-800-274-2237, extension 4100 or swaldren@aafp.org.

Sincerely,

Jeffrey J. Cain, MD, FAAFP
Board Chair