AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

May 28, 2015

Secretary Sylvia M. Burwell,
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell,

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I write in response to the proposed rule titled, "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications" as published in the March 30, 2015 *Federal Register*.

The AAFP appreciates that the U.S. Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator (ONC) for Health Information Technology seek public comments to improve healthcare and the way electronic health information is shared. The AAFP continues to encourage our members to adopt electronic health records to provide better patient care. However, our longstanding concerns persist with the increasingly challenging Meaningful Use requirements. Since the initiation of the Meaningful Use program, there have been fundamental changes to move aggressively toward value-based payment. The transition to value-based payment will require extensive changes within the health care system.

We believe that health IT certification is necessary, but current efforts to achieve that certification create barriers toward interoperability within the health care system. Payments and incentives for vendors and providers must be modified and aligned with the goals of interoperability for continuity of care, care coordination, and portability of patient records. Many current payment and other regulations are based on fee-for-service and paper-based record systems and we believe these regulations and policies should be revised to reflect the movement toward value-based payments. We are now in the fourth year of certified EHR technology and do not see wide-scale improvements in interoperability. Without modernizing and aligning business drivers, the AAFP does not believe interoperability will be achieved. To facilitate interoperability, we recommend that certified vendors who fail to meet interoperability standards or, participate in any form of information blocking, face significant and sustained penalties for such actions. We believe it is time for HHS to apply economic pressure on vendors as a motivator to accelerate interoperability.

The AAFP strongly supports the proposal to have a Common Clinical Data Set. The AAFP was instrumental in establishing a common clinical summary data set in 2005 through work with ASTM and others that established the Continuity of Care Record standard. We support a robust certification framework to test for

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the ability of health IT to create such a data set. We also encourage HHS to test for the ability to parse and compute a received data set. Furthermore, the AAFP urges restraint on what data is mandatory for each exchange of the clinical common data set. Family physicians often experience the unintended consequences of overly specific requirements of what should be in a data set (i.e. clinical summary exchange) without the ability of their certified EHR technology to parse and interpret the incoming data. Physicians receive voluminous summaries with a myriad of non-clinically relevant data for patients for certain episodes of continuity of care. Without the certified EHR technology to assist in providing a common data summary, physicians must view the entire summary on the screen and manually extract and often manually re-enter the key information into the patient's record. That is not the level of interoperability we should expect from new certification requirements since our members could use faxes and avoid spending several thousand dollars on upgrades to the 2015 certified edition of their EHR. Vendors should be held accountable for fully meeting this standard and should be subject to monetary penalties if they do not.

We are confused with the CMS proposal to adopt a "2015 edition base EHR" since the certification process is moving toward a modular certification, which the AAFP continues to support. In prior versions of the certification, there was a designation for a complete EHR. This told the consumer that the certified "product," which in many cases is multiple products certified together, would provide the functionality needed to achieve Meaningful Use. Since a "2015 edition base EHR" designation would not provide the purchaser/user with the assurance of having what is needed to achieve Meaningful Use, the AAFP does not understand what value is added by the designation and we are therefore concerned about the potential confusion with the prior complete EHR designation. We are also concerned that some of the functionality included in the "2015 edition base EHR" is not appropriate for a base product. Namely, we do not believe that the functionality around implantable devices should be part of any base designation. We therefore object to these proposed changes.

We strongly support ONC's proposal to "modify the ONC Health IT Certification Program in ways that would further open access to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond the ambulatory and inpatient settings." Our members have experienced the struggle to fulfill the interoperability requirements of Meaningful Use where the other exchange party (e.g. public health or state immunization registry) is not required to use the same standards as certified EHR technology. Extending certification would support interoperability among all players in the health care system.

The proposed rule states, "we propose to require that ONC-ACBs report to the National Coordinator complaints received on certified health IT." The AAFP supports this proposal. There needs to be post-market surveillance of certified products to ensure continued compliance with certification criteria in real-world implementations. The AAFP does believe there needs to be penalties for health IT vendors that perform information blocking. We are not against decertification, but we do believe that physicians using the product should be held harmless and we therefore support and urge you to provide a multi-year exemption from Meaningful Use penalties. We also believe that financial penalties to vendors could be a good interim step.

Regarding clinical decision support, the proposed rule states, "we propose to require that a Health IT Module must be able to identify linked referential CDS information using the Infobutton standard only." We have concern with restricting this by including the word "only." Requiring the use of a standard such as the Infobutton standard is helpful, but stating that it is the sole way to achieve a desired result is problematic

since it stifles innovation. We urge HHS to strike “only” and rather require the compliance with the Infobutton standard.

The AAFP is very supportive of the Application Programming Interface (API) certification requirements within the proposed rule. However, it is important to understand that APIs alone do not stop information blocking behavior by vendors. The AAFP believes HHS must ensure appropriate access to these APIs by proper providers and patients.

We appreciate the opportunity to provide these comments. Please contact Steven E. Waldren, MD, MS, Director, Alliance for eHealth Innovation at 800-274-2237, extension 4100 or swaldren@aafp.org.

Sincerely,

Reid B. Blackwelder, MD, FAAFP
Board Chair