May 29, 2015

Assistant Secretary Karen DeSalvo  
Office of the National Coordinator for Health Information Technology  
Attention: RIN 0991-AB93  
Hubert H. Humphrey Building  
Suite 729D  
200 Independence Ave., SW  
Washington, DC 20201


Dear Assistant Secretary DeSalvo:

The American Academy of Pediatrics (AAP), a non-profit professional organization of more than 64,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults, appreciates the opportunity to comment on the 2015 Edition Health Information Technology (Health IT) Certification Criteria, the 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Modifications.

The AAP is committed to the meaningful adoption of health information technology (HIT) for improving the quality of care for children and commends the comprehensive approach being taken by the Office of the National Coordinator for Health Information Technology (ONC) to streamline and improve the 2015 Edition Health IT Certification Criterion (CEHRT). There is tremendous potential for Health IT to facilitate patient safety and quality improvement, specifically quality measurement and reporting through efficient data collection, analysis and information exchange.

The AAP has been involved in programmatic activities aimed to improve pediatric functionality in EHRs over the course of the last decade. We are one of the founding organizations of the Continuity of Care Record (CCR) effort that was the original way that interoperability was achieved. We have also published pediatric specific requirements for ePrescribing as well as inpatient and outpatient HIT systems. The AAP also worked with Agency for Healthcare Research and Quality (AHRQ) and CMS as a subcontractor to develop the Model Pediatric EHR Format. We continue to be involved in subsequent ongoing work to identify and enhance critical pediatric EHR functionality outlined within the original format. Finally, the AAP is also working closely with the Centers for Disease Control and Prevention (CDC) on how to best incorporate immunizations into EHRs.
The AAP appreciates this opportunity to comment on the proposed CEHRT and has the following suggestions on the proposed rule:

**Executive Summary - Innovation**
One of the purposes of the regulatory action as stated in the Executive Summary is that it will “provide Health IT developers with more flexibility and opportunities for certification that support both interoperability and innovation.” The AAP would like to see explicitly how the new guidelines will promote innovation and interoperability, perhaps by including a section that states the flexibility and opportunities in these new requirements. A section with more details in the full document will enable developers and users to clearly see and take advantage of these opportunities.

**III.A.3.w – Electronic Prescribing (e-Prescribing)**
While the AAP is indeed a supporter of metric standard overall, we are concerned with the proposal that a Health IT Module be capable of limiting a user’s ability to electronically prescribe all medications in only the metric standard. Not all medications, particularly topical ones, are easily prescribed in metric dosage. Some examples include eye drops, ear drops, insulin, etc. Therefore, the AAP would urge the ONC to soften the language in this proposal to exclude topical medications from the CEHRT requirement that all medications must be prescribed in metric units.

**III.A.3.r – Social, Psychological and Behavioral Data**
The AAP agrees with the goal of this proposed requirement to address health disparities by providing certification standards for the collection of social, psychological, and behavioral data, including the exchange of sensitive health information including sexual orientation, as it has the potential to address the health needs of sexual minority children and teenagers. While we approve of this attempt to address challenges related to sexual orientation and gender identity, the AAP opposes any requirement that patients commit to a gender or a sexual orientation. Teens in particular may not be comfortable selecting a particular label for their gender identity or sexuality. Many pediatricians speak to teens in gender neutral terms in order to address sexual activity properly. Therefore, although we agree with the requirement of adding EHR fields to better address gender and sexuality, we are concerned that forced categorization may be damaging to the patient-provider relationship.

**III.A.3.s – Decision Support: Knowledge Artifact**
The AAP strongly favors these decision support requirements and the establishment of certification criteria in the 2015 Edition for technology to electronically send and receive clinical decision support knowledge artifacts in accordance with a Health eDecisions (HeD) standard.

**III.A.3.t – Decision Support: Service**
The AAP also strongly supports this type of decision support, which allows for technology to electronically make an information request with patient data and, in return, receive electronic clinical guidance in accordance with an HeD standard. However, we also believe that decision support as a web service should also be an acceptable way of exchanging knowledge. If there is a desire to lighten the requirement on vendors, the AAP feels that pediatricians will prefer that a
vendor is able to utilize knowledge as a remote service rather than implementing a knowledge artifact feature.

III.A.3.u – Transition of Care
Transitioning care is crucially important for pediatricians and their patients, and the AAP believes that it is important to include more specific language on the requirements for transition of care for children with special health care needs such as Neonatal Intensive Care Unit (NICU) graduates and medically complex children. For example, NICU graduates should be provided with useful information about their NICU course, and specific follow-up plans that move them to the care of a primary care provider. Additionally, such specific information will be necessary to transfer the care of teenagers with complex medical needs into adult care.

III.A.3.ddd – Safety Enhanced Design
The AAP would like to see more details on the processes that will be implemented under this measure, meant to enhance patient safety and reduce risk for patient harm. User-centered design (UCD) processes need to transcend a heuristic or empirical view. UCD is much more complex than the mere testing requirements of the National Institute of Standards and Design (NIST) guidelines that are referred to in the proposed rule. One such example is in validating that the functional requirements are actually appropriate for the intended workflow, meaning that the task that has been tested or validated must be functional for the actual end workflow. The AAP suggests that UCD processes should be related to functional requirement, and not just relegated to formal testing.

Alignment of the Model Electronic Health Record Format and CEHRT Requirements
As mentioned, the AAP has worked closely with the Agency for Healthcare Research and Quality (AHRQ) as a subcontractor to develop the Model Pediatric EHR Format and continues to be involved in subsequent work to identify and enhance critical pediatric EHR functionality outlined within the original format. The AAP recommends that the Model EHR format be included within the CEHRT requirements. The development of the Model EHR format represents an essential step in assuring pediatric functionality within EHRs as it contains a set of child-specific requirements (and other requirements of special importance for children) that an electronic health record (EHR) should meet to perform optimally for the particular needs of children.

Reporting Thresholds
The AAP is pleased that the ONC has removed the need to report thresholds for many requirements. For example, § 170.315(e)(1) (View, download, and transmit to 3rd party) or VDT, is now considered to be one or greater than one patient. The AAP feels that this is a needed change for pediatricians as it makes it more favorable for pediatricians to qualify for the 2015 CEHRT.

Reporting Data to Outside Entities
The AAP is concerned that there is not enough emphasis on the bidirectional reporting of clinical data to outside entities within the proposed rule. For example, many pediatricians practice in areas and states where their counterparts cannot accept bidirectional data from Immunization Information Systems (IIS). Many pediatricians do not report clinical data to cancer registries or
outside entities because these outside entities do not want pediatrician data. We are pleased that there appears to be some forgiveness during attestation if providers are unable to share data, but we are concerned that with other types of providers moving toward connectivity while sharing data with one another will leave pediatricians behind.

Additionally, the AAP suggests that the ONC work with the Centers for Disease Control and Prevention (CDC) to accept influenza statistics electronically. This would be acceptable for surveillance as many pediatricians participate in the CDC’s influenza-like illness (ILI) program, but the CDC will not accept the data electronically.

**Tobacco Language**
The AAP suggests expanding the term “smoking status” with more inclusive language to capture smokeless tobacco and nicotine use. Recent evidence suggests that young people, especially adolescents and early adolescents, are using smokeless tobacco and nicotine products at a higher rate than cigarettes. This includes such products as e-cigarettes which use liquid nicotine. Though there was an objective specific to smoking status in Meaningful Use Stage 2, there is no objective in Stage 3 because CEHRT requires smoking status as a criterion.

Additionally, the AAP would like to see CEHRT account for secondhand smoke exposure. Often, pediatricians ask the parents or children if they live in a home with someone who smokes, or if the child spend any time with someone who smokes. CEHRT should require that systems are able to capture this information so that pediatricians can provide the appropriate guidance to patients and parents in order to protect children from the dangers of secondhand smoke.

**Food Insecurity**
The AAP supports a standardized way to document food insecurity in EHRs. Good nutrition is essential to support the foundations of child health, growth and development. Today our children are experiencing an unprecedented nutritional crisis resulting in the double burden of obesity and food insecurity and hunger. Nearly 1 in 3 school-age children and adolescents is overweight or obese, and only half of all children ages 2 to 17 meet federal diet quality standards. Obese children are at increased risk for high blood pressure, high cholesterol, cardiovascular disease, type 2 diabetes, sleep apnea, asthma, joint problems, fatty liver disease, and social and psychological problems. In order to address the basic needs of proper nutrition for children we recommend the inclusion of a hunger and food insecurity questionnaire in standard EHR products.

The United States Department of Agriculture (USDA) currently uses the Household Food Security Scale (HFSS), an 18-item measure to assess food insecurity within the home. However, a more practical in-office tool is the two-question screen designed by Hager et al. This format uses two questions from the HFSS:

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1. “Within the past 12 months we worried whether our food would run out before we got money to buy more,” and
2. Within the past 12 months the food we bought just didn’t last and we didn’t have money to get more.”

Affirmative answers to these two questions identified food insecurity with a sensitivity of 97% and a specificity of 83% as compared to the full 18-item HFSS. The AAP recommends that this simple, two question screening be standard in EHR products.

The AAP appreciates the opportunity to provide comments on the ONC’s proposed rule on 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Modifications. The Academy is committed to the meaningful adoption of HIT for improving the quality of care for children and looks forward to continuing to work with ONC to ensure that CEHRT is implemented in a way that promotes the goals of improving the quality, safety and cost-effectiveness of care. If we may provide further information or assistance, please contact Patrick Johnson in our Washington, DC office at (202) 347-8600 or pjjohnson@aap.org.

Sincerely,

Sandra G. Hassink, MD, FAAP
President

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