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November 6, 2015

The Honorable Karen DeSalvo

Office of the National Coordinator for Health Information Technology

Attention: Interoperability Advisory Standards

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 Office of the National Coordinator for Health Information Technology's (ONC) "2016 Interoperability Standards Advisory (ISA)."

The AAP is committed to the meaningful adoption of health information technology for improving the quality of care for children, and appreciates the approach being taken by the ONC to, "coordinate the identification, assessment and determination of the best available interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs." There is tremendous potential for HIT 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 the 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 outlined pediatric specific requirements for ePrescribing as well as inpatient and outpatient HIT systems. The AAP also worked with the Agency for Healthcare Research and Quality (AHRQ) and Centers for Medicare and Medicaid Services (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.

The AAP appreciates the ONC's effort in producing these interoperability standards. However, while the document covers a wide variety of topics that need to be addressed when examining interoperability, we wish to address some gaps in the standards. We believe that appropriate interoperability standards can make care for children more effective, safer, and less costly, and therefore, would like to draw the ONC's attention to the following elements of the ISA.

Identifiable Gaps in the ISA

Transfer of birth and newborn data to the medical home: It is important that interoperability standards include the ability to transfer information on pregnancy as well as birth data from a mother's medical record, as well as a newborn nursery record, including newborn screening, to the medical home. While it may be possible to address this as a simple transfer of care using a CDA, it is important to highlight that this is a complex task that is essential for all children. Treatment and anticipatory care of a child requires critical information regarding complex mother-infant links. The AAP believes that this functionality should be mandatory, and should be addressed in the ISA.

Inclusion of preventive health schedules: The AAP recognizes and appreciates your intent to include surveys and data entry templates in future work. However, we believe that this should be generalized to include preventive health schedules, including AAP's Bright Futures, as well as individual state Early and Periodic Screening, Diagnostic, and Testing (EPSDT). By generalizing standards, EHR vendors will be free from the need to custom implement each survey, and will enable pediatricians to enhance and update their EHRs at little or no cost.

Privacy and confidentiality of patients: The AAP is concerned about the privacy and confidentiality needs of adolescents, children in foster care, and children with special needs. These privacy needs should always be an important part of considerations for security of interoperability and these children should never be excluded from benefiting from health information exchange because of lack of security and privacy protection they require.

Lack of harmonization between internal and external data: The AAP has received reports from pediatricians that the adoption and benefit from interoperability may be limited by the lack of harmonization between the external representation of information in standard messages and documents, and the internal representation of the same information within the EHR. This makes it difficult or impossible to incorporate and use data sent using standards without manual transcription and re-keying of data. Some examples include: medications prescribed at an emergency department visit, immunizations recorded in an immunization registry, or newborn lab screening results. The AAP recommends using the HL7 FHIR approach to standard data objects and resources as a strategy for overcoming this problem.

Lack of incorporation of data into EHRs: As the ONC is aware, adoption of interoperability requires more than just sending and receiving data using standard messages and codes. It is important that the information be incorporated, be searchable, and used within the EHR. Unfortunately, this is not happening for many of our pediatricians at this time. The AAP believes that assessments of adoption of interoperability standards should include a separate assessment of whether the standards are sent and received, and whether the data transmitted has been discretely imported into an EHR and used for computations. Too much of the interoperability we see in use today does not really advance electronic data transmission beyond what was achieved in the past using paper and fax machines with data scanned into an EHR as a document. It is not enough to simply send an Emergency Department visit note, or transmit a previous growth chart. Rather, pediatricians must be able to see new medications on a medication list, or see old height and weight measurements plotted on the same growth chart as new measurements.

Questions and Requests for Stakeholder Feedback

General

4-1. In the 2015 Advisory, each standard and implementation specification was listed under a “purpose.” Prior public comments and HIT Standards Committee recommendations suggested that the Advisory should convey a clearer link to the ways in which standards need to support business and functional requirements. This draft attempts to do so and lists standards and implementation specifications under more descriptive “interoperability needs.” Please provide feedback on whether revision from “purpose” to “interoperability need” provides the additional requested context and suggestions for how to continue to improve this portion.

The AAP believes that the revision for “purpose” to “interoperability need” is indeed appropriate, and emphasizes that interoperability should be needs driven as well as result in changes in care as a result of being able to use data from a variety of sources. Most of the interoperability needs of children are addressed in the current document, but additional suggestions are discussed above in our introductory comments.

4-2. For each standard and implementation specification there are six assessment characteristics. Please review the information provided in each of these tables and check for accuracy. Also, please help complete any missing or “unknown” information.

The AAP feels that the assessment of adoption should look separately at the process of sending and receiving the data and at discrete import of data into systems that will use them computationally.

4-3. For each standard and implementation specifications, there is a table that lists security patterns. This draft only includes select examples for how this section would be populated in the future. Please review examples found in Sections III-A and III-F and provide feedback as to the usefulness of this approach and any information you know for a specific interoperability need.

The AAP does not have a specific comment on this at this time, but would like to reiterate that the protection of adolescent privacy is an important concern to integrate into several of the interoperability needs.

4-4. For each interoperability need, there is a table beneath the standards and implementation specifications that includes limitations, dependencies, and preconditions. This draft only includes select examples for how this section would be populated in the future. Please review populated sections and provide feedback as to the usefulness of this approach and any specific information you know for a specific interoperability need.

The AAP would like to emphasize that exploration and documentation of limitations is a critical step to identifying gaps in standards and their ability to serve the needs of children. Though we are currently unable to provide specific feedback on each example, we hope to provide more specific feedback in the future. There are numerous current challenges in this areas, including: the differences between using ICD-10 CM and SNOWMED CT for problem lists, and using NDC for new prescriptions and RXNORM for medication history. Unfortunately, too few EHRs

support dual coding, therefore limitations arise when systems focus on one approach to meet business needs, thereby not fully meeting clinical needs which may be better served by using an alternate coding approach. Additionally, it is important that we identify more specific examples of where these limitations impinge on the clinical care provided for certain medical conditions.

Section I: Vocabulary/Code Set

4-5. Based on public feedback and HIT Standards Committee review, there does not appear to be a best available standard for several “interoperability needs” expressed in this section of the draft Advisory. Please provide feedback on whether this is correct or recommend a standard (and your accompanying rationale).

With regard to immunizations, the AAP is pleased that you have recommended use of NDC codes for vaccines administered. The AAP would like to point out that the CDC has mapped NDC codes from the FDA to their CVX and MVX codes and furthermore that they have also mapped CVX codes to one or more vaccine groups that enable tracking of vaccines that may be components of multiple target vaccines or vaccine targets that have many alternative products on the market

Section II: Content / Structure

4-6. Should more generalized survey instruments such as the IHE Profile Retrieve Form for Data Capture be considered?

The AAP believes that more generalized survey instruments should be considered, and that this is a very important gap in the standards that should be included among interoperability needs. Surveys, questionnaires, and scales are an important part of pediatric practice, and they are frequently used in well-child care. The AAP does not wish to comment specifically on the IHE profile, but we will continue to explore this and other options for building data capture forms are part of the work of our Council on Clinical Information Technology. Currently, the Council is building an EHR Template Library, and it will send information and comments to the HIT Standards Committee for use in preparing the 2017 ISA.

4-9. The HIT Standards Committee recommended to ONC that clearer implementation guidance is required. Are there additional implementation specifications that should be considered for this interoperability need?

The AAP will send future comments to the HIT Standards Committee on this topic, and will also work towards filling gaps such as an implementation guide for birth data and newborn screening.

Section III: Services

4-10. The 2015 Advisory’s Section III, Transport has since been removed with content representation migrated as applicable within Section IV Services. What is your view of this approach?

The AAP believes that this approach works regarding current approaches to transport.

Appendix II: Sources of Security Standards

4-11. Are there other authoritative sources for Security Standards that should be included in Appendix II?

The AAP does not have any additional security standards to add at this time. However, we wish to reiterate the important of two special privacy concerns in pediatrics that should be an important test of the adequacy of current approaches to security standards. The first, adolescent privacy, is particularly important for privacy portals and which has been a barrier to implementing systems. The second is privacy for children with foster care, wherein the needs of the child must be balanced with the need for privacy and confidentiality. The AAP has important policy statements on these issues. It is important that we are able to assure appropriate privacy and confidentiality for children when recommending security standards.

The AAP appreciates the opportunity to provide comments on the ONC's Interoperability Standards Advisory for 2016. 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 the ONC to ensure that interoperability 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 pjohnson@aap.org.

Sincerely,


Sandra G. Hassink, MD, FAAP
President

SGH/arp