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July 31, 2017

The Honorable Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW
Floor 7
Washington, DC 20201

RE: Proposed Interoperability Standards Measurement Framework

Dear Dr. Rucker:

The American Academy of Pediatrics (AAP), a non-profit professional organization of more than 66,000 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) 2017 Interoperability Standards Measurement Framework.

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 ONC to identify the essential elements that should be examined when considering nationwide interoperability. 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, and the AAP believes that interoperability standards measurement is key to realizing this potential.

The AAP applauds the ONC's effort in encouraging interoperability, and is pleased to see that it is seeking feedback on the Interoperability Standards Measurement Framework. As the ONC notes, there are both opportunities and barriers to implementing interoperability standards, and that AAP is pleased to provide feedback from the pediatric perspective.

The AAP is providing the following answers to the proposed questions:

1. Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system's value to stakeholders?

The Academy is wary of solely relying on a voluntary-based measure reporting system. It is critical that the ONC be cognizant that not all barriers to interoperability are technical in nature. Although some stakeholders may have the technical capability to participate in a voluntary, industry-based measure reporting system, they may be hesitant to do so for a variety of reasons, including:

- not having the money or resources to implement or support ongoing exchange with multiple outside stakeholders;
- not seeing the perceived value in measure reporting because the majority of their information that they find useful already exists within their health system;
- wanting to control their network and steer patients to use all providers within their existing system;
- doing the minimum required on their own end, but not wanting to institute the inbound side because they have not yet figured out a way to efficiently handle additional inbound information.

Another existing problem is that in a competitive HIT market, there is a lack of business incentive to achieve interoperability across different HIT systems, such as between different electronic health records (EHRs). There should be built-in incentives to provide affordable interoperability instead of just requiring vendors to provide interfaces that facilitate the comprehensive secure exchange of health information.

2. What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?

The AAP is supportive of ONC's proposal to annually survey the industry. We believe that it would be helpful in determining the appropriate incentives that would achieve interoperability as well as perceived barriers from industry's perspective.

It is also critical that ONC recognize that there is a wide variability in adherence to data vocabularies and standards, and that there is "messy" old data that often breaks functionality. For example: taking a patient chart that is ten years older than the standards themselves and creating Clinical Document Architecture (CDA) that often contains old data that makes the functionality break under the particularly brittle standards. The AAP believes that the ONC should ensure that there is an alternative mechanism that allows for more flexibility of older data that vendors do not have the time or resources to continue to trouble shoot differences in how other systems have handled it.

3. Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?

As we have seen with Immunization Registries, there is wide variability in third parties utilizing data exchange, wherein each case is unique, and uses their own version of the data set or delivery method. Some states require Social Security numbers for patient matching and some states will only take complete data. We are now seeing this with Health Information Exchanges (HIE) and other exchange stakeholders, wherein some entities want some data in one format and some data

in another format, packaged together, and provided at varying intervals. Additionally, we see that HIE's often make the determination that they want the data presented differently. Clearly this is not sustainable for vendors. Additionally, when one of the partners in the data exchange updates or changes their requirements, they often do not proactively reach out to their data exchange partners, and ultimately, the end user client is the one who notices that the data feeds are broken.

To ameliorate these issues, the AAP believes that ONC should define the best evidence-based metrics that demonstrate the value of interoperability and effective framework that provide the outcomes that point out the return on investment from a care quality perspective and cost perspective.

4. What, if any gaps exist in the proposed measurement framework?

The AAP applauds the ONC for its comprehensive interoperability standards measurement framework proposal. This proposal outlines the necessary elements and possible challenges to measuring the implementation and use of interoperability standards. We have also identified opportunities where we feel it would be beneficial to expand the measurement framework. For instance, the AAP suggests that the framework include specific measures for care quality and cost savings. We believe measuring how providing a robust health information exchange can improve patient care and reduce costs for practices will help secure nationwide interoperability. Additionally, as more institutions move to the cloud, security problems arise with outside entities for ACOs, HIEs, and other groups who want data periodically pulled. Vendors cannot allow just anyone into their cloud environment, but it is also not sustainable to keep pulling the data in this "one at a time" fashion.

5. Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?

The AAP agrees that a multi-pronged approach to measurement and collecting data from multiple industry stakeholders is necessary to accurately measure the implementation and use of interoperability strategies. Specially, we believe the ONC's approach to collect data from surveys and HIT developers, exchange networks, and self-reporting stakeholders will be largely successful. We believe that it is critical that pediatrician stakeholders are included in this primary group. Pediatricians have unique needs and challenges in Health IT, and efforts to proceed in interoperability efforts without them will lead to gaps in the data.

There are also opportunities to improve the measurement framework by expanding the network of stakeholders supporting the collection of data. For instance, industry experts, such as health economists, legal analysts, and public health specialists, could provide critical support for data collection and analysis. We therefore encourage the ONC to leverage the talent of other health specialists as well as the identified stakeholders to support data collection.

6. Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in this report? If not, what challenges might they face in developing and reporting on these measures?

The AAP recognizes that there may be significant challenges for stakeholders collecting and exchanging data to develop and report on these measures. For instance, there is often no financial sustainability model for building, testing, and maintaining data exchanges. This is especially burdensome for pediatricians, because third parties decline to pay for small practices to exchange data.

Another possible challenge is that stakeholders may require agreements that data use would not be used purely for competitive advantage. For instance, HIT developers and exchange networks may not want to publicly report on their development plans. We therefore encourage the ONC to consider these challenges for stakeholders when reviewing the proposed framework.

Finally, there are issues surrounding adolescent confidentiality. Unfortunately, there are no acceptable or widely employed standards for data exchange related to adolescents. In many places, children thirteen and older are simply left out. This represents a very large portion of the pediatric population that has not been addressed appropriately. Even if one system can keep the information confidential, often the receiver cannot, and there, it is not safe to send.

7. Ideally, the implementation and use of interoperability standards could be reported on annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?

The AAP appreciates this document's focus on stakeholders publicly reporting the implementation of interoperability standards, and agrees that this reporting will help facilitate public and private cooperation in achieving interoperability goals. Furthermore, we believe that reporting on the implementation and/or use of interoperability standards on an annual basis is feasible. However, the potential challenges to achieving this goal should be considered when developing reporting requirements. For instance, a complicated reporting system may add significant administrative costs to practices. The AAP recognizes the importance of tracking the implementation of these standards, but is concerned that the administrative costs of doing so could be passed on to the patient. We therefore suggest that the ONC considers which stakeholders will incur the cost of tracking and reporting the implementation of interoperability standards when developing this framework. As we approach achieving nationwide interoperability and improving patient care, the AAP suggests that the effects of increasing reporting system complexity also be considered moving forward.

The AAP is also concerned about non-adherence to the standards. While EHR vendors are certified for data exchange, outside parties are not, and therefore they are not being held accountable for not adhering to data standards. There are still labs that do not use Logical Observation Identifiers Names and Codes (LOINC) and IIS codes that require abnormal fields. The AAP is concerned that if these are not certified, we cannot be sure that the data is meaningful.

8. Given that it will likely not be possible to apply the measurement framework to all available standards, what process should be put in place to determine the standards that should be monitored?

The AAP appreciates this document's focus on building a measurement framework that prioritizes standards that are integral to achieving the goal of nationwide interoperability. We agree that it will likely not be possible to apply the measurement framework to all available standards, and have therefore identified areas that the ONC should prioritize. For instance, we believe that it will be essential to monitor how user-friendly these interoperability platforms are. If these platforms are not easily accessible to stakeholders, this will present a major barrier to achieving nationwide interoperability. Next, the AAP also believes that the ONC should monitor standards associated with health quality and cost outcomes. It is important to measure health quality and cost outcomes to ensure that interoperability results in patients receiving better care.

Finally, it is critical that ONC be cognizant of the vendor issues associated with tracking. Many EHR vendors have a mix of client server and cloud clients, which would require the vendors to develop tracking mechanisms that would be able to give this information to the ONC. Once again, the AAP is concerned about the costs and financial sustainability associated with complying with these requirements.

9. How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?

The AAP appreciates that the ONC plans to consult data holders when building measurement standards. We suggest that the ONC convenes a diverse panel representative of stakeholders to determine the framework of these measures, and that this panel contains a pediatrician. If convening a panel is not feasible, the AAP still believes that discussing these measures in other settings, such as at an industry meeting, will be integral to building a successful standards measurement framework. In addition, this framework must identify clear definitions of these measures in order to ensure consistent reporting.

The AAP is concerned, however, about the lack of resource support required for reporting. There will undoubtedly be costs associated with extra tracking and reporting at the vendor levels, and vendors could pass these costs on to clients, which could further add a burden to practices who are already balancing the complex equation of paying for additional technology without seeing a reduction in payment for patient care.

10. What measures should be used to track the level of "conformance" with or customization of standards after implementation in the field?

The AAP agrees that it is important to track the level of "conformance" with or customization of standards after implementation in the field. In addition, we recognize that various measures could successfully track the level of conformance to standards and encourage the ONC to choose measures that demonstrate conformance with meaningful and accepted outcomes.

In conclusion, the AAP urges the ONC to ensure that you are including pediatricians at every level of development and implementation of these standards. Pediatricians have unique needs due to their patient population. Children are not just little adults, and therefore pediatricians need different tools to ensure that they are receiving the best care possible. As you continue to develop the Interoperability Standards Measurement Framework, the AAP encourages you to consider pediatric functionalities in exchanges including: vaccines, preventative health measures, growth charts, care team functionalities, and birth history data collection and transfer. The ONC efforts should be sure to support the concept of the medical home.

The AAP appreciates the opportunity to provide comments on the ONC's "Proposed Interoperability Standards Measurement Framework." The AAP 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 you have any questions, please contact Patrick Johnson in our Washington, DC office at 202/347-8600 or pjohnson@aap.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Fernando Stein". The signature is stylized with a large, sweeping loop at the top and a long, thin tail extending downwards and to the left.

Fernando Stein, MD, FAAP
President, American Academy of Pediatrics

FS/arp