June 3, 2019

Donald Rucker, MD National Coordinator Office of the National Coordinator for Health Information Technology Department of Health and Human Services Mary E. Switzer Building 330 C Street SW Washington, DC 20201

RE: RIN 0955-AA01: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear National Coordinator Rucker:

Our organizations—which represent physicians, nurses, hospitals, public health professionals, and other stakeholders—encourage the Office of the National Coordinator for Health Information Technology (ONC) to prioritize patient safety as part of its efforts to implement new criteria for electronic health records (EHRs) used in the care of children.

Given that the care of children can differ significantly from that of adults, the technology used by clinicians should account for that variation. For example, children often receive medication doses based on their weight. Similarly, chronological or gestational age may be used for medication dosing in highly vulnerable premature infants. The EHRs used to prescribe those drugs should account for these critical dosing differences, which—coupled with the use of technology that is not geared towards these unique variations—can contribute to medical errors in pediatric care.

Safety problems associated with the use of EHRs in pediatrics often stem from system usability, which refers to how the technology can be effectively and efficiently used by clinicians. System layout, customizations, facility workflows, and many other factors can affect EHR usability for pediatric providers.

Poor usability can have significant negative consequences. It can contribute to clinician burden when using systems, which can harm the efficiency and quality of care. Poor usability can also contribute to medical errors. Research published in the November 2018 edition of *Health Affairs* showed that EHR usability contributed to medication errors in 3,243 of 9,000 safety events examined across just three health care organizations that care for children.¹ Additionally, recent examples of EHR usability-related medical errors showcased pediatric-specific challenges, such as with newborn care and weight-based dosing.²

Recognizing this challenge, Congress—via the 21st Century Cures Act (Cures) passed in 2016—required ONC to establish voluntary certification criteria for EHRs used in pediatric settings. To implement this provision, the ONC proposed rule identifies 10 clinical priorities for pediatric care. ONC also included worksheets to map each of these clinical priorities to existing and proposed requirements for EHRs. For example, ONC proposes that EHRs used in pediatric care should have the ability to compute the weight-based dosage of a medication and could use EHR functions for electronic drug prescribing with pediatric vital signs to meet this clinical priority.

While we generally support the 10 clinical priorities identified by ONC for pediatric care, including weight-based drug dosing, tools to support growth charts for children, and age-based dose checking, we

assert the agency can take additional steps to improve patient safety and system usability for EHRs used in the care of children. These include:

• Mapping additional existing EHR certification requirements to pediatrics

ONC should further extend the approach taken in the proposed rule to map the agency's existing EHR certification requirements to pediatric care. For example, ONC currently requires that all EHR developers test their system using predefined scenarios that mimic real-world situations. ONC should clarify that demonstrating adherence to the 10 clinical priorities must involve pediatric-focused scenarios. Similarly, ONC currently requires that EHR developers test their system with end-users, such as physicians and nurses. ONC should clarify that EHR developers must involve end-users that care for children—such as pediatricians and pediatric nurses—in the testing of the identified clinical priorities in pediatric care.

Providing additional pediatric-focused resources

ONC should ensure that the appropriate resources are available to support meeting pediatricfocused criteria. For example, ONC should develop specific and detailed guidance for each proposed pediatric clinical priority. In addition, ONC should involve pediatric usability experts in the development of implementation guides and test procedures for the pediatric clinical priorities.

Conclusion

Cures directed ONC to address deficiencies in the use of technology in pediatric settings. By incorporating these additional recommendations into its development of a pediatric EHR certification program, ONC can take concrete steps to improve the usability of EHRs used in pediatric care to both reduce clinician burden and prevent medical errors.

Thank you for the opportunity to comment on the proposed rule to implement new criteria for EHRs used in the care of children. Should you have any questions or if we can be of further assistance, please contact Ben Moscovitch, director, health information technology, The Pew Charitable Trusts at bmoscovitch@pewtrusts.org or 202.540.6333.

Sincerely,

American Academy of Pediatrics American Nurses Association Arkansas Children's Hospital Children's Hospital Association Drummond Group Medical Group Management Association MedStar Health Patient-Centered Primary Care Collaborative The Pew Charitable Trusts The University of Texas, UT Health Austin

¹ Raj M. Ratwani et al., "Identifying Electronic Health Record Usability and Safety Challenges in Pediatric Settings," *Health Affairs* 37, no. 11 (2018: 1752-1759, <u>https://doi.org/10.1377/hlthaff.2018.0699</u>.

² The Pew Charitable Trusts, "Poor Usability of Electronic Health Records Can Lead to Drug Errors, Jeopardizing Pediatric Patients," (April 2019), <u>https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2019/04/poor-usability-of-electronic-health-records-can-lead-to-drug-errors-jeopardizing-pediatric-patients.</u>