



June 3, 2019

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  
200 Independence Avenue, S.W.  
Washington, D.C. 20201  
ID: HHS-ONC- 2019-0002-0001, RIN 0955-AA01

Submitted electronically at: <https://www.regulations.gov/>

Dear Dr. Rucker:

Thank you for the opportunity to provide comments on the Proposed Rule to implement provisions of the 21st Century Cures Act Electronic Health Record Reporting Program.

The Alliance for Nursing Informatics (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represents more than 20,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 4 million nurses in practice today. We have reviewed the Proposed Rules and we offer our comments as nursing stakeholders.

ANI strongly endorses the provisions in the 21<sup>st</sup> Century Cures Act, designed to advance interoperability and address occurrences of information blocking. ANI previously provided [recommendations to support the achievement of the 21st Century Cures objectives](#), which included increased attention to implementation processes, a patient-centered focus, and increased engagement of stakeholders across the care continuum. Therefore, ANI applauds the ONC's solicitous work in support of the 21<sup>st</sup> Century Cures Act by engaging stakeholders in the public and private sector and addressing ongoing concerns related to clinicians' administrative burden, EHR usability and barriers to information exchange.

Having reviewed the proposed rules, we offer **two overarching recommendations** to the Office of the National Coordinator (ONC) to promote achievement of the key 21st Century Cures provisions:

- 1. Increase Transparency in Health IT System Performance and How Health IT Systems Meet Certification Criteria**
- 2. Engage Nurses from Diverse Specialties as Key Stakeholders in the Development of Systems, Measures and Criteria**

Our detailed rationale, and more specific comments on the provisions of the proposed rule, are included below.

## **1. Increase Transparency in Health IT System Performance and How Health IT Systems Meet Certification Criteria**

Long recognized as the most honest, ethical and trusted professional,<sup>1</sup> nurses play a significant role in patient engagement, patient safety and care quality. Patient advocacy has been central to nursing since the dawn of the profession.<sup>2</sup> As such, ANI strongly supports the overall emphasis and overall approach presented in the proposed rule, and the attention to patient rights to access their health data. We endorse many of the proposed provisions to reduce information blocking, and to improve patient safety and quality of care through increased interoperability and health information exchange.

A key concept to achieve these objectives from the 21<sup>st</sup> Century Cures Act is transparency. Transparency is paramount to patient engagement and care quality, and crucial to ensure that electronic health information is stored, accessed, exchanged or used in reasonable and non-discriminatory manner. ANI strongly supports proposed provisions to increase transparency, including the two new privacy and security transparency attestation certification criteria, and mandatory disclosures requirements. We encourage the ONC to prioritize the finalization of these provisions.

ANI enthusiastically endorses the proposed provisions to reduce information blocking, and concurs that the proposed exceptions to these provisions are reasonable. However, we express concern related to how to determine that practices falling under these exceptions are implemented in a consistent and non-discriminatory manner. ANI suggests that increased transparency will enable a more thorough comparison of the performance of different health IT vendors and systems, and facilitate the determination of consistent and non-discriminatory practices.

## **2. Engage Nurses from Diverse Specialties as Key Stakeholders in the Development of Systems, Measures and Criteria**

As the largest of the healthcare professions,<sup>3</sup> working on the frontlines of healthcare across the care continuum, nurses play a substantial role in the design, collection, exchange and use of electronic health information. A growing body of literature has identified significant issues with usability of information systems and a discordance between these systems and nurses' daily workflow, across all healthcare settings. Research also indicates that active participation and leadership of nurses in the development, implementation and evaluation of health information technology can substantially improve its performance and impact on patient safety, healthcare cost and waste reduction.<sup>4</sup>

ANI emphasizes that policies on healthcare, health information systems, and the access, use and exchange of healthcare data should be driven by evidence and expertise from patients and healthcare professionals, as the key stakeholders, rather than health IT vendors. We encourage a shift in emphasis to assure that patients, clinicians, and researchers – rather than health IT developers – dictate which

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<sup>1</sup> "For the 17th Year in a Row, Nurses Top Gallup's Poll of Most Trusted Profession," AHA News, January 9, 2019, <https://www.aha.org/news/insights-and-analysis/2019-01-09-17th-year-row-nurses-top-gallups-poll-most-trusted-profession>.

<sup>2</sup> Lois Gerber, "Understanding the Nurse's Role as a Patient Advocate," *Nursing* 2019 48, no. 4 (April 2018): 55, <https://doi.org/10.1097/01.NURSE.0000531007.02224.65>.

<sup>3</sup> Institute of Medicine (US) Roundtable on Evidence-Based Medicine, "Healthcare Professionals," in *Leadership Commitments to Improve Value in Healthcare: Finding Common Ground: Workshop Summary* (Washington, D.C.: National Academies Press (US), 2009), <https://www.ncbi.nlm.nih.gov/books/NBK52843/>.

<sup>4</sup> Nancy Stagers et al., "Nursing-Centric Technology and Usability A Call to Action," *Computers, Informatics, Nursing: CIN* 33, no. 8 (August 2015): 325–32, <https://doi.org/10.1097/CIN.000000000000180>; Susan McBride et al., "Statewide Study to Assess Nurses' Experiences With Meaningful Use-Based Electronic Health Records," *Computers, Informatics, Nursing: CIN* 35, no. 1 (January 2017): 18–28, <https://doi.org/10.1097/CIN.000000000000290>.

data are available for access, exchange, and use. ANI encourages engagement of nurses from diverse specialties to further develop certain provisions of the proposed rules:

- For **Sec. 4001**, focused on health IT for use by pediatric health providers to support the health care of children, ANI endorses the new certification criteria as well as the additional voluntary certification criteria. ANI expresses two specific concerns with this criteria. Firstly, we find that practices around segmented access to information and transferable access authority require further development, particularly with the unique needs of adolescent patients coming to the age of majority in mind. Secondly, we endorse the criteria of associating mother's demographics with newborns, but note that this may need to be expanded to also include relevant laboratory findings, including Group B Streptococcus test results and blood type.

We encourage the ONC to engage nursing experts to address these concerns and offer our professional nursing support and informatics expertise services. Our ANI member organizations include experts in the fields of nursing informatics, women's health, obstetric and neonatal nursing, and school nursing, which could significantly contribute to further regulatory and/or non-regulatory initiatives to support health IT for pediatric care.

- For **Sec. 4002**, we endorse the focus areas of new and ongoing criteria for conditions and maintenance of certification. We support the adoption of USCDI as the minimum needed data elements for health care coordination and interoperable health information exchange. ANI reiterates our previous recommendations to ensure that the data captured within these data classes are representative of the needs of patients and the interdisciplinary clinical care team, rather than favoring one discipline. We have also emphasized the importance of real world testing in previous public comments. The ANI offers professional nursing expertise to support these provisions, including the following:
  - Examination of clinical workflows and documentation processes
  - Pilot testing of systems and measures
  - Ongoing real- and near-real-time testing

ANI appreciates the opportunity to offer our comments to advance health IT to reduce information blocking and improve interoperability, with broad ranging implications to the health of the US population. We are available and interested in supporting future public responses on these important healthcare issues.

Sincerely,



Susan Hull, MSN, RN-BC, NEA-BC, FAMIA  
ANI Co-chair



Mary Beth Mitchell, MSN, RN, BC, CPHIMS  
ANI Co-chair

The [Alliance for Nursing Informatics](#) (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a

collaboration of organizations that represents more than 20,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 4 million nurses in practice today. [Contact ANI.](#)