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May 1, 2019

Don Rucker, M.D.

National Coordinator

Office of the National Coordinator for Health Information Technology

U.S. Department of Health and Human Services

200 Independence Ave., S.W.

Washington, D.C. 20201

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

Dear Dr. Rucker,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 36,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy. All of these disorders require coordination of care between neurologists and primary care physicians. Further, many neurologic disorders, especially at early stages, require care coordination, including multiple visits with various providers. Issues associated with data blocking and EHR interoperability can add additional challenges.

The AAN is committed to efforts that will streamline EHR interoperability and reduce data blocking. Challenges associated with interoperability and information blocking are two of the most critical challenges forcing clinicians to spend more time on low-value clerical work and less time on direct patient care. Consistent policies are needed across the board to incentivize and facilitate the exchange of data across systems. Many EHRs do not support the robust use of application program interfaces (APIs) for data exchange or are hindered by APIs that are implemented in proprietary ways that inhibit data exchange.

The AAN appreciates the Department of Health and Human Services' (HHS) and the Office of National Coordinator's (ONC) commitment to addressing information blocking and interoperability. Overcoming the burdens inherent to transitioning to an interoperable electronic health landscape and addressing the detrimental impact of data blocking on patient care are significant priorities for the AAN. The sharing of health

information that is needed to coordinate care and improve health outcomes, especially for patients with complex medical needs, requires seamless interoperability between different EHR platforms. While the proposed rule is an admirable step in the right direction towards interoperability, compliance with the rule must be attainable without shifting the burden of cost and implementation to providers.

Exceptions to Information Blocking Prohibition and Defining Information Blocking

The AAN appreciates that it is difficult for ONC to define information blocking in a manner that would comprehensively cover all instances of inappropriate information blocking. The AAN also agrees that there are certain limited cases in which the blocking of transmission of electronic health information (EHI) is necessary and appropriate. As such, the AAN supports ONC's baseline expectation that "actors should be required to share EHI unless they are prohibited from doing so under an existing law or are covered by one of the exceptions."¹

Although the AAN would appreciate additional concrete guidance on what constitutes information blocking and would appreciate ONC continuing to provide and update examples of practices that would implicate the information blocking provision, the AAN understands that defining information blocking is likely to be an iterative process that is impacted by rapidly changing technology and use cases. The AAN notes that the exceptions to information blocking each contain a number of conditions, all of which must be met for an individual exception to apply. The AAN notes that the exceptions are often described with terms like "reasonable," which can be vague and open to interpretation.

The AAN is appreciative of ONC's discussion of practices that are likely to interfere with, prevent, or materially discourage access, exchange or use of EHI. The AAN supports the five categories that ONC has identified as likely to interfere with the exchange of EHI: (1) restrictions on access, exchange or use; (2) limiting or restricting the interoperability of health IT; (3) impeding innovations and advancements in access exchange or use of health IT-enabled care delivery; (4) rent-seeking and other opportunistic pricing practices; and (5) nonstandard implementation practices.²

Additionally, the AAN supports ONC's broad definition of EHI that incorporates both electronic protected health information as defined under HIPAA and "any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted or maintained in electronic media ... that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."³

Preventing Harm Exception

The proposed rule states that, an exception to the information blocking prohibition may exist in cases in which "a licensed health care professional has determined, in the exercise of

¹ 84 Fed Reg. 7523

² 84 Fed Reg. 7518-7521

³ 84 Fed Reg. 7513

professional judgment, that the disclosure is reasonably likely to endanger the life or physical safety of the patient or another person.”⁴ The AAN supports a robust exception for cases in which information blocking is reasonable and necessary to prevent physical harm to a patient or another person.

Although the AAN supports this proposed exception, the AAN believes that it may not be comprehensive enough. The AAN is concerned with the safety impact of open API disclosure of highly sensitive patient data, like genetic testing results. The AAN firmly believes that discretion is of the utmost importance in cases in which the results of high-risk genetic tests are conveyed to patients. In cases in which test results implicate a very high-rate of developing a neurodegenerative disease for which there is no cure or effective treatment, like Huntington’s disease, the AAN believes an exception to data sharing requirements is appropriate to ensure that patients and their families are not exposed to this information without appropriate counseling and context. The AAN requests clarity on whether genetic testing results for diseases like Huntington’s would be protected by the above exception.

If not covered by the preventing harm exception as currently drafted, the AAN recommends that ONC expand this exception so that the results of genetic tests for Huntington’s and other diseases implicating a high rate of developing a neurodegenerative disease are exempted from the information blocking prohibition until such information can be disclosed in the most clinically appropriate manner. Organizational policies in which a clinician chooses not to release the test result electronically and plans to deliver the result to the patient in a clinically appropriate manner must be protected and are consistent with the conclusions of relevant research.⁵

Cost Recovery Exception

The AAN appreciates ONC providing examples associated with cost recovery that would implicate the information blocking provision. The AAN also appreciates ONC’s statement that “a broad or insufficiently tailored exception for the recovery of costs could protect rent-seeking, opportunistic fees, and exclusionary practices that interfere with the access, exchange, and use of EHI.”⁶ The AAN is concerned with the proposed permittance of covered entities to impose fees on individual requests for copies of PHI. The AAN believes this will detrimentally impact patient access to PHI and is an example of the rent seeking behavior that ONC is hoping to avoid. Additionally, the AAN requests further clarity on how the reasonableness of fees will be determined. ONC provides several examples of impermissible fees, but the AAN believes that the discussion of reasonable fees in the proposed rule is vague and could undercut ONC’s intent to prevent rent-seeking and opportunistic fees.

Responding to Infeasible Requests Exception

The AAN supports the proposed exception for responding to requests that are infeasible. The AAN appreciates that there are likely to be cases in which complying with an information

⁴ 84 Fed Reg. 7524

⁵ MacLeod et al, Recommendations for the predictive genetic test in Huntington’s disease Clin Genet 2013;83:221-231.

⁶ 84 Fed Reg. 7538

sharing request in the specific manner requested would be cost prohibitive and appreciates this exception accounting for substantial and unreasonable burdens in the form of high costs.

Without Special Effort

As ONC notes, one of the most consequential phrases in the 21st Century Cures Act relates to the need for deployment and use of APIs “without special effort.” The AAN appreciates ONC’s effort to give further clarity on its interpretation of “without special effort.” Although the AAN supports promoting a healthcare ecosystem predicated on the three attributes described in the proposed rule: standardized, transparent and pro-competitive, the AAN finds the lack of a firm definition of “without special effort” to be problematic and open to interpretation.

Complete Access to EHI

The AAN asks ONC to define the term “complete access to EHI” as it is a critical element of defining interoperability overall as well as potential exceptions. Complete access is suggested to involve “providing patients with their EHI; enabling the use of EHI for treatment and care coordination; and making EHI available for quality improvement and population health management activities”⁷ but a concrete definition is not established in the proposed rule.

Disincentives for Health Care Providers Request for Information

In the proposed rule, there is a request for information on potential disincentives to be placed on providers found to be engaging in information blocking. While the AAN does not have concrete suggestions for what these disincentives should look like, we note that disincentives should only be applied to actions that are within the control and knowledge of the provider. Disincentives should also only be applied that are known to the provider at the time that the inappropriate conduct occurred. Additionally, the AAN suggests the establishment of a remedy period for providers to come into compliance with the information blocking restriction, and avoid disincentives, in cases in which there has been no immediate material or physical harm to patients.

Data from Legacy Systems

The AAN supports efforts to advance the use of standardized, Fast Healthcare Interoperability Resources (FHIR) based APIs for patients to gain access to their health information. Patient access through open APIs to data including claims data, laboratory results, medications, and clinical notes is critically important to care coordination and to improving a patient’s overall understanding of their health and course of treatment. Although the AAN supports improved access to this data, the AAN requests further clarification on how data that predates this rulemaking will be treated. Will patient data from legacy systems be required to meet the updated FHIR standard? The AAN is concerned that a requirement to update legacy EHI data to the new standard may be significantly burdensome on providers and practices. It is critical that these requirements are implemented without shifting

⁷ 84 Fed Reg. 7543

additional administrative burden to healthcare providers. The AAN supports vendors being required to implement these new standards, including potential legacy EHI, in a manner that should not place additional burden on provider and end-user configuration. Additionally, the AAN notes that implementation of these requirements should consider provider usability and efficiency so that this update does not unduly add to provider cognitive burden.

USCDI Standard

The AAN supports adoption of the USCDI standard to require a minimum set of data classes that are required for nationwide interoperability. The AAN supports this effort and takes note of the fact that the 2015 Edition includes a data class for clinical notes. The AAN supports efforts that would improve patient access to their clinical notes.

Certification Standards

The AAN supports many of the proposed certification standards. The AAN strongly supports the certification criteria associated with EHI export. Switching EHR systems is a time consuming and expensive activity for providers. The AAN supports ONC's efforts to reduce administrative burden by requiring health IT developers to implement the capability to export all EHI they produce and electronically manage in a computable format. This will be significant and helpful both for individual patient data requests and when providers change systems.

The AAN also strongly supports the real-world testing certification standard. The AAN notes that real-world testing is required by the 21st Century Cures Act. The AAN believes that it is important for health IT to be consistently real-world tested to demonstrate it is functioning properly in the intended use cases and in the practice setting for which it is intended.

The AAN supports the new pediatric EHR certifications to account for the unique needs of pediatric patients. The AAN also supports the proposal to include conduct that has the effect of prohibiting or restricting protected communication about health IT as subject to the Conditions of Certification. It is important that providers are free to discuss issues associated with health IT systems. Agreements restricting these communications are known to be unsafe, anti-competitive and can hinder innovation. The AAN appreciates the provision that would require health IT developers to notify their customers that communication blocking contract language that predates this rulemaking will not be enforced.

Patient Matching Request for Information

The AAN supports efforts to improve patient matching and to establish a comprehensive standard for identifying and matching patient records. The AAN understands that a universal patient identifier has been statutorily banned but believes some standard should be in place to allow for the matching of patient records across systems.⁸ In the absence of a universal patient identifier, the AAN recommends using 2-3 unique patient data elements for the purpose of matching patients.

⁸ 84 Fed Reg. 7656

Trusted Exchange Network

The AAN supports ONC's proposal for a new Condition of Certification that would require health IT developers to participate in the Trusted Exchange Framework and Common Agreement (TEFCA). The AAN concurs with ONC that the TEFCA is the most appropriate standard for the trusted exchange network. This is necessary to ensure that developers are not engaging in information blocking.

Interoperability with Referrals

The AAN acknowledges the existing 2015 Edition certification criteria to support care coordination, and electronically send, receive, and securely transmit health information. The AAN would like to note that the proposed interoperability rules (including clinical notes, provenance, and data segmentation in the concept of a dynamic shared care plan) should also support transparency and interoperability for referrals throughout the healthcare system.

Neurologists play a key role as specialists who both receive referrals and often make referrals in their practice. The current lack of interoperability standards limits neurologists' abilities to efficiently refer patients for clinical care between care team members and to communicate efficiently before scheduling, and between visits. We advocate that the ONC consider having referrals transparency be a use case as part of care coordination. The AAN has been and is a participant in the American College of Physicians' High Value Care Coordination project and would welcome standards that would better support the transfer and communication of clinical information of relevance during the process of making, assessing, scheduling, and communicating about referrals as a key activity requiring dynamic interoperability during care coordination.

Qualified Clinical Data Registries

The AAN appreciates ONC's attention to the critical role that qualified clinical data registries (QCDRs) play in collecting and analyzing clinical outcomes data to identify best practices and improve patient care. Access to patient data from EHRs is critical for QCDRs to achieve these goals. As ONC recognizes in the proposed rule, EHR vendors often create impediments to sharing information with registries. The principal impediments to integration of EHR data into clinical data registries are that some EHR companies refuse to share their data with registries or are charging excessive fees for this data exchange. These barriers interfere with and materially discourage access to information. Imposing these barriers on the exchange of data are particularly inappropriate given that EHR vendors act as intermediaries for health care providers who seek to submit data to clinical data registries.

Additionally, the AAN urges ONC to adopt the definition of "clinician-led clinical data registries" included in the Cures Act in future rulemaking to implement Section 4005 of the Cures Act.

Conclusion

Addressing the ongoing challenges related to interoperability and data blocking is a top priority for the AAN. The AAN appreciates ONC's continued engagement and commitment on this issue. The AAN believes that the policies outlined in this proposal are a significant step toward a more interoperable health IT landscape. The AAN is committed to continued engagement with the administration as the health care system works to combat information blocking and improve the exchange of information.

Thank you for the opportunity to provide comments on this proposed rule. Please contact Matt Kerschner, the AAN's Government Relations Manager, at mkerschner@aan.com or Daniel Spirn, the AAN's Senior Regulatory Counsel, at dspirn@aan.com with any questions or requests for additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Sacco", written in a cursive style.

Ralph L. Sacco, MD, MS, FAHA, FAAN
President, American Academy of Neurology