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
330 C Street, SW
Washington, DC 20201


Dear Dr. Rucker:


PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to also educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI is committed to advancing policies that protect the ability of patients to receive high-quality care and is supportive of advancing policies that promote interoperability and patients' access to their health information. Interoperability and the unimpeded flow of information, for both physicians and their patients, is critical to ensuring the delivery of coordinated, high-quality, and necessary health care.
Overview
Under Title IV of the 21st Century Cures Act, ONC is responsible for advancing policies that promote interoperability, support the access, exchange, use of electronic health information, and address information blocking. The policies presented in this proposed rule focus on improving patient and provider access to electronic health information, as well as promoting competition. More specifically, ONC is proposing policies related to: Conditions and Maintenance of Certification Requirements for health IT developers; exceptions to the information blocking provision; permitted fees Application Programming Interfaces (API) technology suppliers and API data providers can charge; API certification criteria and associated conditions of certification; new United States Core Data for Interoperability (USCDI) standard; electronic health information (EHI) export requirement for EHRs; health IT certification criteria and standards for pediatric care and practice settings; and the standards version advancement process.

PAI commends the ONC on taking steps to advance new policies that address these longstanding challenges and barriers. We believe that it is important to empower patients and physicians with comprehensive health information files to help them make more informed decisions. We especially believe in giving patients more visibility into their treatment records and making their information more transparent to them so they can truly be partners in their care.

PAI provides comments in response to the specific policies proposed in this rule. However, more broadly, we urge the ONC to take the following specific recommendations into consideration as it proceeds with implementing the policies:

- Vendors should have accountability for ineffective exchange of information and their products; additionally, health care delivery systems should be accountable for delaying, withholding, or limiting data from being displayed, provided, or shared across platforms. This will relieve undue pressure on physicians.

- Costs for updating information systems and health IT to the new standards and requirements should not be passed on to physicians and patients. Physicians and patients have little influence on the speed with which these exchanges are implemented and have minimal control over accelerating the process. Many vendors have delayed their updates and continue charging practices exorbitant fees for these updates, even when they are delayed or not completed.

- Bi-directional information access, exchange, and use of health information for authorized purposes is important for interoperability and care decisions; interoperability is not achieved with one-way access.

- Broad exceptions to information blocking should not be permitted as these exceptions could be manipulated to further support and continue current information blocking practices; additional clarification is necessary on the specific instances in which an exception may be used.
Continuous stakeholder engagement should remain a key focus, specifically with state medical societies who hear directly from physician membership about the associated difficulties and burdens; these societies can provide valuable insight into recommended updates and changes at the data collection, display, review and connectivity phases of medical record data usage.

Interoperability Definition
ONC is proposing the following definition for interoperability, consistent with the 21st Century Cures Act definition:

Interoperability means health IT that: 1) enables the secure exchange of electronic health information (EHI) with, and use of EHI from, other health IT without special effort on the part of the user; (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and (3) does not constitute information blocking.

PAI is supportive of this definition of interoperability. Interoperability should allow for complete access, exchange, and use of all patient health information, across health IT systems, without undue burden or effort by the user and without certain information being withheld by certain entities or providers. Furthermore, it is important to clarify and modify the definition to include bi-directional access, exchange, and use of health information for authorized purposes.

Adoption of the U.S. Core Data for Interoperability (USCDI) as a Standard
Currently, ONC has adopted the 2015 Edition “Common Clinical Data Set” (CCDS) interoperability definition and used the CCDS in certification criteria. However, given varying uses of the CCDS coupled with the transition towards value-based care, the ONC believes that a new definition and standard would be appropriate. ONC is proposing to remove the CCDS and to adopt the USCDI Version 1 standard for 2015 Edition, which requires baseline data classes, including: assessment and plan of treatment; care team members; clinical notes; goals; health concerns; immunizations; lab tests and results; medications; patient demographics; problems; procedures; provenance; smoking status; UDI for implantable devices; and vital signs.

PAI is supportive of adopting the USCDI as a standard and related data classes. We also believe that standardization of the display conventions of the data classes and elements would be helpful. Standardization would only be as effective as its adopters, and PAI urges the ONC to ensure that it occurs across settings, vendors, and stakeholders.

However, the USCDI includes many new data classes and elements that vendors will need to incorporate into their systems. PAI is concerned that the costs for updating to the new standard may be passed onto physicians. We urge the ONC to ensure that these costs are not passed on directly to the users who already incur high investment costs and fees for obtaining and maintaining their electronic health records (EHRs). Additionally, we believe it would be helpful to require collection of
social determinants of health (SDOH) data and other patient characteristic and demographic data (e.g., race, ethnicity, socioeconomic status, etc.). These should be included as part of the new standard to help better inform care decisions and more comprehensive patient profiles/records.

2015 Edition Certified EHR Technology (CEHRT) Criteria

ONC is proposing to remove the 2014 Edition criteria and making the 2015 Edition criteria the baseline for health IT certification. Furthermore, ONC is proposing to remove the following specific criteria for 2015 Edition CEHRT: Problem list; Medication list; Medication allergy list; Smoking status; Drug formulary and drug list checks; Patient-specific education resource; Common clinical data set summary record – create and receive; and Secure messaging. ONC is also proposing to add the following new criteria: Consent management for application programming interfaces; Encrypt authentication credentials certification criterion; and Multi-factor authentication criterion.

PAI is supportive of eliminating inconsistencies and costs associated with having two different Editions. However, we emphasize the need to ensure that, with the elimination of the 2014 Edition as an option, vendors and developers be required to expeditiously update systems to the 2015 Edition so physicians can comply with Quality Payment Program (QPP) requirements. PAI also urges against permitting vendors to charge physicians exorbitant fees to “upgrade” from 2014 to 2015 Edition or for updating their 2015 Edition CEHRT to reflect the revised criteria.

PAI also has concerns with the criteria that is being proposed for removal. While the ONC believes that some of these functionalities will continue to be offered even if they are removed as certification criteria, PAI is concerned that this may not hold true. These are critical pieces of data that should be collected/captured and shared in patients’ medical records.

EHI Export and Transitions Between Health Systems

ONC is proposing to require health IT developers to provide the capability to electronically export all electronic health information (EHI) produced. Specifically, ONC is proposing the following requirements for health IT vendors: 1) EHI produced and electronically managed must be readily available for export upon a single patient’s request for their health data and/or for all patients when a provider seeks to change health IT systems; and 2) the export file must be computable and include documentation (via a publicly available hyperlink) for interpretation and use of EHI. ONC is permitting developers flexibility in how they implement the export functionality for transitions between systems, but also makes them responsible for ensuring that this is done in way that enables and supports customers and third-party contractors to successfully migrate data.

PAI agrees with the ONC that switching EHR systems is time consuming and expensive for physicians as well as patients. Thus, PAI is supportive of efforts to decrease this burden and to support more seamless transfers of information between systems. However, we reiterate our concern that the associated cost of this functionality could be passed onto users. Neither physicians nor patients should pay for export or access to data that they are producing.

Additionally, PAI understands the need for providing developers with some flexibility based on their systems. However, we encourage the ONC to ensure that this is done in a timely manner and holds
developers to certain expectations and deadlines for ensuring successful transitions between systems. We also believe that it is important to extend this beyond developers and require this of other entities that often serve in the “vendor” role for physician access to health IT (e.g., health systems and hospitals).

**Conditions and Maintenance of Certification**

The 21st Century Cures Act requires ONC to establish Conditions and Maintenance of Certification requirements. ONC is proposing seven Conditions and Maintenance of Certification requirements with corresponding maintenance requirements for health IT developers and entities. These include: Information blocking; Assurances; Communications; APIs; Real world testing; Attestations; and EHR reporting criteria submission. Under the “assurances” requirement, health IT developers of certified health IT must provide an assurance that the certified capabilities have been made available in ways that makes them implementable and usable for their intended purposes.

PAI is supportive of these seven Conditions and Maintenance of Certification requirements. Specifically, we would like to highlight the importance of the “assurances” and “communications” requirements. PAI is very supportive of requiring developers to satisfy these conditions and ensuring that they have not taking actions or prohibited communications that could interfere with the usability of the systems for their intended purposes.

**Information Blocking**

The 21st Century Cures Act added the information blocking provision, which was enacted to ensure that the availability, exchange, or use of EHI for authorized and permitted reasons was not being unreasonably limited. A practice implicates the information blocking provision if it is “likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.” The ONC is proposing to establish seven exceptions to the information blocking provision for providers, health IT developers, health information exchanges (HIEs), and health information networks (HINs). These exceptions are: 1) Preventing physical harm to patient or another person; 2) Promoting privacy of EHI; 3) Promoting security of EHI; 4) Recovering costs reasonably incurred for providing access, exchange, or use of EHI; 5) Responding to “infeasible” request for EHI; 6) Licensing interoperability elements on reasonable and non-discriminatory terms (e.g., royalties); and 7) Maintaining and improving health IT performance (must be temporary).

PAI has concerns with these broad exceptions to information blocking. While PAI understands ONC’s reasoning and intent for allowing these exceptions, many exceptions can be manipulated to further support and continue current information blocking practices. For example, health systems and hospitals often cite liability as well as security and privacy concerns as a reason for limiting physician access to EHI even though the practice is due to information blocking. We believe that additional details and scenarios/examples within each of these categories should be defined to clarify the specific instances in which an exception may be used. Furthermore, we believe that an application/approval process similar to the application process physicians must use for exceptions to the MIPS Promoting Interoperability category should be utilized.
Application Programming Interfaces (APIs)

ONC is proposing a new certification criterion for APIs by requiring health IT developers to support API-enabled services for data on single and multiple patients. API suppliers must make business and technical documentation freely and publicly accessible to interact with their APIs. This includes fees, restrictions, limitations, obligations, software application registration process requirements, and any other information needed to develop, distribute, deploy and use applications to interact with the API. Furthermore, API suppliers must promote an open and competitive marketplace by: 1) Granting API data providers authority and autonomy to permit users to interact with the API technology; 2) Upon request, grant API data providers and users rights reasonably necessary to access and use API in a production environment; 3) Make reasonable efforts to maintain compatibility of API; and 4) provide API based on objective and verifiable criteria, but not based on whether user is an existing/potential competitor or revenue/value user may derive.

PAI is supportive of ONC requiring API-enabled services, and for developing and implementing APIs in an open and competitive manner. PAI is also supportive of making this information freely and publicly available to ensure increased patient access to their health information. However, PAI cautions that patient information should remain within patients’ control. While other parties may also require access to patient records, patients should have some ability to limit or restrict their data, for example, through an “opt out” process or some other vehicle for patient decision making or patient approval or disapproval.

API Supplier Fees

ONC is proposing to prohibit API suppliers from charging fees that support the use of an API that facilitates a patient’s ability to access, exchange, or use their EHI, or charging fees to users except for “value-added services.” API suppliers may charge fees to API data providers (i.e., organizations that deploy the API technology).

PAI supports prohibiting API suppliers from charging fees to users. However, we believe that “value-added services” could be a catchall phrase that could prevent access to certain information (i.e., implicate the information blocking provision). We believe that “value-added services” needs to be better defined and what is included/excluded be better clarified.

API Data Provider Fees

ONC is proposing to permit API data providers to charge fees to offset costs incurred to deploy, maintain, and enable use of the API. However, the fee must not implicate information blocking. The following compliance method is being proposed for the fees:

- Objective, verifiable criteria that are uniformly applied must be basis for the fees/costs;
- Fee/Costs must be reasonably related to providing API-based access, exchange, or use to, or at request of, the API user;
- Fees/Costs must be allocated among all users;
- Fees/Costs cannot be based on whether the user is an existing or potential competitor;
Fees/Costs cannot be based on sales, profits, revenue, or other value that the user can derive from accessing, exchanging, or using the data.

PAI is supportive of ensuring of these conditions, especially that the fees not implicate information blocking and that they are not based on potential value a user may derive from the data. We believe it is important that physicians and patients continue to have access to necessary EHI and related data to make informed decisions, and that financial barriers should not contribute to access issues.

**Request for Information (RFI) on Exchange with Registries**

ONC is seeking input on how standards-based APIs can be used for exchange with registries for a range of purposes, including public health, quality reporting, and care quality improvement.

PAI believes that bi-directional information exchange is critical for coordinated and more informed patient care. We believe the communication back and forth between systems needs to better define and outline the data elements that should be shared and how and in what level of detail. For example, for diagnostic and procedural coding, all lab data should be exchanged, including the results, ordering provider, order date, order purpose, etc. Additionally, we believe it would be helpful to make available any SDOH, patient characteristic, and demographic data (e.g., race, ethnicity, socioeconomic status, etc.) as these are also relevant to patient health and care decisions.

The Agency should also consider leveraging existing infrastructure and HIEs to support interoperability rather than recreating the wheel. There needs to be more coordination and cooperation between state and federal agencies on how HIT and related funds are allocated for data submission and use. Additional funding and support are also necessary on the physician and provider side to adopt and implement capabilities that would allow them to connect to interoperable systems.

**Patient Matching RFI**

One of the current barriers to interoperability and patient care is patient matching, which can help centralize patients' EHI in a single file/resource. ONC is seeking input on opportunities for patient matching that can contribute towards coordinated care efforts.

PAI believes that patient matching is critical so both patients and their physicians can have access to a holistic view into the patient’s health and would allow both parties to make more informed care decisions. Matching claims and encounter data would allow physicians to get a more holistic look at patient health profiles and make decisions based on the totality of the care patients are receiving across the spectrum of medical and health care services. We believe in giving patients more visibility into their medical records and making their information more transparent to them so they can truly be partners in their care.

However, a key component to patient matching is standardization of data elements and a greater focus on data matching. PAI believes that streamlining the reporting requirements, collection standards, identifying common data elements for state, federal, and other programs, and identifying specific data fields would support better patient matching. However, these efforts should be done with stakeholder input, especially those who must enter the data and who must rely on the data for
The delivery of health care services is a cross-sector model and it is important that the different requirements from each of the sectors be incorporated and aligned within the EHR and health IT elements of the delivery model.

**Conclusion**

Overall, PAI supports CMS’ efforts to streamline and reduce unnecessary burdens placed on physicians related to EHRs, interoperability, and health IT. These adjustments must benefit all physicians and providers equally and not be designed or structured simply for large health systems or to the disadvantage of small practices. Additionally, it is critical to ensure that physicians’ costs for providing care to patients not increase as a result of the policies finalized from this proposed rule. EHR and other vendors and third parties are responsible for complying with the policies resulting from this proposed rule and there should be safeguards in place to ensure that their costs are not passed on downstream to physicians and patients.

We welcome the opportunity to work with the ONC to further implement and advance strategies and efforts to reduce burden in a meaningful and impactful way. If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI’s Executive Vice President and CEO, at k2strategiesllc@gmail.com.

Sincerely,

Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute