AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

June 3, 2019

**VIA ELECTRONIC MAIL**
regulations.gov

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services (HHS)

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

Dear Dr. Rucker,

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to provide the following comments in response to the Office of the National Coordinator (ONC)'s proposed rule on interoperability, "information blocking" and health information technology (health IT) certification. Our organization is the policy voice of five Seventh-day Adventist affiliated health systems that include 85 hospitals and more than 300 other health facilities in 17 states.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. With such diverse facilities, populations served and geographical locations, we strive to provide an objective and sound health policy voice that is relevant across state lines and sectors of care.

Below, please find AHPA's comments and recommendations on the ONC's proposed interoperability rule. Specifically, we comment on the following issue areas:

- Information Blocking
- Updates to the Certified Electronic Health Records Requirements
    - Adoption of USCDI Standard
    - Export of Electronic Health Information
    - Scope of Electronic Health Information
- Conditions and Maintenance of Certification
    - Application Programming Interfaces
    - New Certification Criterion
- Health IT Developers of Certified Health IT
- Price Information

## Information Blocking

The ONC proposes the following seven exceptions to the current "information blocking" prohibitions on health care providers, health IT developers, exchanges and networks:

1. Preventing harm to a patient or another individual;
2. Promoting the privacy of Electronic Health Information (EHI), including any measures required to comply with the HIPAA Privacy Rule;
3. Promoting the security of EHI, including measures needed to protect its confidentiality, integrity and availability;
4. Recovering costs reasonably incurred in providing access, exchange or use of EHI (excluding charging fees for individuals' access to their own information);
5. Not responding to requests that are infeasible, including requests that impose a substantial burden considering the provider or other actor's circumstances (such as size and resources);
6. Licensing of interoperability elements on reasonable and nondiscriminatory terms;
7. Maintaining and improving health IT performance in ways that make it temporarily unavailable.

The burden would be on the actor, the entity accused of "information blocking," to prove that one of the proposed exceptions applies to their case.

**AHPA affirms the seven exceptions proposed for "information blocking" prohibitions and commends the ONC for its efforts to increase competition and promote patient access to data.** We believe that patients' EHI, as well as the ability to access it, should not be sold back to patients by the custodians of said data. By continuing its work to reduce "information blocking," the ONC discourages vendors from charging exorbitant interoperability fees or engaging in other anti-competitive practices.

**AHPA recommends that the ONC adopt an additional exception for data requests unrelated to patient care.** For example, providers should not be required to share EHI with commercial enterprises for them to use for marketing purposes. The exchange of data among providers, health IT developers, exchanges and networks should be conducted for the sole purpose of improving patient care. We believe a more nuanced discussion is needed surrounding the business-case reasons for requesting EHI. Particularly, we are concerned about bulk requests for large swaths of patient data from outside entities without a reasonable business case.

**Additionally, any exchange of EHI should maintain the privacy of patients. Therefore, AHPA opposes any requirement that mandates the disclosure of patient data with non-covered HIPAA entities.** This requirement would necessitate additional regulations outlining the circumstances for mandated disclosure and increase administrative burden for both the requestor and the responder. Each request would need to be evaluated to determine if it met the definition of mandated disclosure. The covered entity receiving the request would also need to set up a new administrative process to confirm the identity of the requester. The liability associated with the mandated disclosure of patient health information to entities that are not subject to HIPAA's privacy and security protections is significant. While we appreciate HHS clarifying in the FAQs that providers will not be liable under HIPAA for sharing information with third-party apps per the request of a patient, such protection does not apply to other non-covered entities that may be interested in obtaining patient data.[1] Furthermore, in many states, obtaining consent from a patient to disclose his or her information is required under state law. Because of these issues, we believe an exception for information blocking is needed for the exchange of EHI with non-covered HIPAA entities and for instances in which patient consent is not granted.

## Updates to the Certified Electronic Health Record Requirements

*Adoption of the USCDI Standard*

The ONC proposes updating the 2015 Certified Electronic Health Record (EHR) requirements to increase standardization, enhance interoperability and improve the accessibility of patient data. The proposal expands the set of data classes and constituent data elements to be shared by naming the United States Core Data for Interoperability (USCDI) Version 1 as the standard. This would increase the minimum baseline that must be commonly available and replace the "Common Clinical Data Set" in the 2015 Edition.

**AHPA supports the adoption of the USCDI Version 1 with the ONC's selected minimum standard of eight note-types, including the new "provenance" data class.** Authorship and authoring-organization information is critical to the trustworthiness of data being exchanged. We support the inclusion of the three new provenance data elements with the following record originating information: "the author," "the author's time-stamp" and "the author's organization." **We would also welcome the inclusion of a data element recording the most recent entity sending the information**, **as this may not necessarily be the original author.** AHPA commends the ONC for its plan to provide stakeholders

[1] Health Information Privacy: HIPAA, Question 572 – "Does A HIPAA-Covered Entity Bear Liability?"

with the opportunity to comment on the expansion of the USCDI standard in the future and looks forward to providing counsel.

*Export of EHI*

The ONC proposes that health IT developers provide the capability to electronically export all EHI. Export capabilities must exist both for single-patient requests as well as for bulk downloads when providers choose to migrate to another health IT system. The data must be in a computable format and include documentation to allow for its interpretation and use. Providers and developers would be required to implement this within 24 months of the final rule's effective date.

**AHPA agrees that all EHR systems should make their EHI available for export in a computable, commercially-reasonable format.** For providers, this would make any necessary transition between EHRs much easier and decrease any practice of veiled "information blocking" by vendors. We also support the ONC's proposed requirement that this capability be patient-focused and easily accessible; however, we anticipate challenges for those providers who use multiple EHR systems. Each EHR vendor may provide this downloadable data in a different format, which may then need to be reconciled for patient use. **AHPA requests clarification and guidance on the responsibility of providers to amalgamate this disparate data into a single record-set for patients to download.**

*Scope of EHI*

For the purpose of exporting information, the ONC defines the scope of EHI as "all EHI that the health IT system produces and electronically manages." This would apply to the entire database and include all data from the oldest to the most recent patient. Clinical data would encompass imaging information, which includes both the image and any accompanying narrative text. The ONC seeks comments on the feasibility, practicality and necessity of exporting images and/or imaging information.

**AHPA requests that images and video produced as a byproduct of procedures, such as images or audio dictation created during a surgery, not be included in the scope of EHI.** These files are typically produced by an individual provider to aid in the performance of a specific medical task. Narrative text often accompanies this data, mirroring its contents, and is already captured in the EHR. The EHR is not traditionally used as the standard storage location for these multimedia files. If this data is to be included in the scope, we ask that a different method for its transmission be developed.

**AHPA also recommends that the ONC provide a clear definition of what EHI must be provided to a patient or entity upon request.** Whether records are in paper or electronic form, they must be reviewed to ensure that there is no additional or unnecessary data included prior to disclosure. A clear and standard definition would help reduce the administrative burden associated with downloading every piece of patient information stored in multiple EHRs and storage locations. Due to the same concern, we seek clarification on whether health providers will be required to provide all EHI available for a patient or whether requests could be tailored to specific timeframes (e.g. 10 years vs. 20 years of data). We find the proposed EHI definition significantly broad, which would result in extremely large downloads that may not facilitate the seamless exchange of information in a timely manner.

## Conditions and Maintenance of Certification

*Application Programming Interfaces*

The ONC proposes the adoption of the HL7® Fast Healthcare Interoperability Resources (FHIR) standard for across all Application Programming Interface (API) technology as a conformance requirement. Due to FHIR Release 4's recent release, the ONC is considering four options for FHIR version adoption:

1. Adopt just FHIR Release 2. Any use of FHIR Release 3 or 4 would occur, at earliest, one year after the final rule is issued.
2. Adopt FHIR Release 2 and FHIR Release 3. Developers would be able to use either one. Any use of FHIR Release 4 would occur one year after the final rule is issued.
3. Adopt FHIR Release 2 and FHIR Release 4.
4. Adopt FHIR Release 4, solely.

**AHPA supports the adoption of FHIR Release 4, the fourth proposed option.** We believe that developers will have all applicable FHIR Release 4 specifications prior to the final rule, which would facilitate the adoption of this standard. We fear that continuing to allow certification under FHIR Release 2 alongside FHIR Release 4 runs counter to the ONC's goal of accelerating progress toward FHIR-based interoperability. Adopting a single standard will make it easier for providers, especially those who contract with multiple EHR vendors, to coordinate between software.

*New API Certification Criterion*

The ONC proposes a new API certification criterion that would require FHIR servers to support API-enabled services for which a single patient's data is at focus and services for which multiple patients' data are at focus (called "population-level" data). The proposed criterion would only mandate support for "read" access for both services.

**AHPA supports the new criterion and urges the ONC to expand to require both read and write capabilities.** Coupled with appropriate security controls, we believe that all EHRs should have the ability to "push" data, inject it discretely and allow other systems to "pull" data. Many times, EHRs have limited read-only APIs that require parties at the source of the data to modify it prior to a request.

## Health IT Developers of Certified Health IT

CMS proposes to define ''health IT developer of certified health IT'' as an individual or entity that *develops* or *offers* health IT.

**AHPA does not support this definition as it would translate into many health care providers being inaccurately identified as health IT developers.** For the purpose of better coordinating patient care, health care systems often offer their EHR to associated physician medical groups. Therefore, under the proposed definition, health care systems would also be considered health IT developers even though they are not engaged in the actual development of health IT.

## Price Information

The ONC seeks comments on the "parameters and implications" of including price information within the scope of EHI for purposes of information blocking. The Agency is considering requiring the inclusion of price information in a patient's EHI, particularly as it relates to the amount paid to a health care provider by a patient as well as payment calculations for the future provision of health care to such patient. Providers that do not include price information in the EHI would be considered information blockers.

**AHPA believes that the ONC does *not* have the statutory authority to require health providers to include price information in their EHI as part of the information blocking requirements.** Provision 42 U.S.C.§300jj-52 of the Social Security Act gives ONC the authority to only create exceptions from what is considered information blocking in the context of EHI. Therefore, while the ONC is authorized to define what is *not* considered information blocking through the use of exceptions, the Agency does not have the authority to expand the definition of information blocking.

**AHPA agrees that price information should be made more readily available to consumers. However, when exploring new requirements, the ONC should take into consideration the different barriers that currently exist to providing price information.** Achieving price transparency is a complex issue because price information is not held solely by hospitals. Information impacting costs, such as a patient's co-payments and deductibles, are held by payers. For example, the cost of a health care service may significantly increase if the patient has not met his or her deductible or if the plan's benefit does not cover the specific procedure. Unfortunately, this information is not always readily available to hospitals. Although the 270/271 Health Plan Eligibility Benefit and Response transactions implemented by the Affordable Care Act (ACA) require insurers to share a plan's benefit information with hospitals, this mandate is rarely enforced.[2] Given the rise of high-deductible plans, having access to a patient's co-payments and deductibles is crucial to providing accurate price estimates. Without addressing this barrier, hospitals are unable to provide accurate price information within the EHI.

Additionally, the ability to share price information is influenced by limitations within a contract to share an insurer's negotiated rates. Doctors and payers generally do not want their negotiated rates to be publicized and it is difficult to provide accurate estimates without doing so. In contracts, there are often clauses that prohibit hospitals from revealing these rates, the violation of which may result in litigation. Due to these contractual restrictions, a requirement for providers to share negotiated rates in their EHRs could result in legal challenges.

**Before implementing new requirements on price transparency, we urge HHS to develop a technical expert panel composed of multi-stakeholder groups responsible for informing the Agency's price transparency efforts.** This will allow the Agency to actively engage in discussions that truly move the needle on price transparency and do not result in unnecessary burdens. Increased consumer demand for

[2] Department of Health and Human Services, 270/271 Companion Guide for NGHP Entities

price information has already sparked many private-market efforts to improve price transparency. For example, AdventHealth, one of AHPA's members, partnered with Simplee to provide patients with personalized price estimates for approximately 300 shoppable procedures across the nine states they serve.[3] Health care systems across the nation as well as insurers continue to innovate in this space with the goal of providing accurate price information to consumers in user-friendly ways. Instead of imposing new regulatory requirements, we encourage HHS to work with these stakeholders and provide a platform to share best practices, co-create solutions and identify potential next steps.

## Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact me at Carlyle.Walton@AdventistHealthPolicy.org or Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AdventHealth.com.

Sincerely,

Carlyle Walton, FACHE
President
Adventist Health Policy Association

[3] The AdventHealth Price Estimator can be viewed here: https://www.adventhealth.com/price-estimator.