



*A Passionate Voice for Compassionate Care*

June 3, 2019

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National Coordinator for Health Information Technology  
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**REF: RIN 0955-AA01**

**21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (84 FR 7424).**

Dear Dr. Rucker:

The Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, sponsors, and related organizations, is pleased to submit these comments on the Office of the National Coordinator for Health Information Technology (ONC) proposed rule on the 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.

CHA supports the goals of improving patient access to their health information and to increasing the interoperability of electronic health across providers and care settings, and appreciates the efforts of ONC to advance this agenda. As ONC moves forward, it is essential to prioritize patient privacy and data security, establish reasonable definitions and standards and minimize unnecessary burdens on providers. We are particularly concerned about the risks involved in providing patients access to their data through third-party applications and tools not subject to the data privacy and security requirements of the Health Insurance Portability and Accountability Act (HIPAA).

- **Updates to the 2015 Edition Criteria**

The proposed rule would make numerous changes to the ONC Health IT Certification 2015 Edition, including removal of certain certification criteria and standards; adoption of the US Core Data for Interoperability standard; addition of a new criterion for electronic health information export; and a new standard for Application Programming Interfaces. **Given the scope of the proposed changes, ONC should establish them as a new edition of certified health technology rather than simply redefining the 2015 Edition.** Confusion among providers who

purchase and use certified health technology could result from very different products available under the same label.

- **Application Programming Interface: Privacy and Security of Patient Data**

The proposed rule would establish new certification standards for Application Programming Interfaces (API), which allow individuals to obtain certain information, including personal health information, from a provider or health plan electronic health record system through third-party application software (an “app”) of their choice. CHA supports the advancement of health information technology to promote easy electronic patient access to the type of information contemplated in the proposal. Further, we appreciate that the proposed API approach supports health care providers having the sole authority to permit connections to their health IT through certified API technology. **However, the privacy of patient information must be paramount, and we are concerned that patient apps are not subject to oversight by ONC or any other federal agency.**

Since 1995 the Health Insurance Portability and Accountability Act (HIPAA) privacy and security provisions have protected patient health information and patients are accustomed to assuming that the privacy of their data is secure. These privacy protections could be rendered meaningless if covered entities such as hospitals, providers and health plans must provide electronic access to protected health information to third-party apps that are not subject to HIPAA requirements. The apps may have limited competency in protecting patient information and may include consent language that allows for greater use of personal data than patients realize.

**We urge ONC to develop an appropriate process for evaluating apps that interact with patient health information and consider a formal vetting or certification requirement.** All patients would benefit from having access to apps that have been evaluated using objective standards. Those who are not English proficient, have lower health literacy, or are less experienced consumers generally are more vulnerable to loss of personal health information through an app that does not provide appropriate privacy and security protections.

- **Conditions and Maintenance of Certification**

ONC proposes a condition of certification that would prevent health IT developers from contractually restricting their users from communicating with others about the usability, interoperability, security, user experience or business practices of the developer. **CHA supports this proposal to prohibit communication restrictions.**

ONC proposes that API Technology Suppliers may only charge API Data Suppliers for use of the certified APIs. We understand that the goal of such a policy is to prevent API Technology Suppliers from charging duplicate fees from both API Users and API Data Suppliers. However, we are concerned that an unintentional consequence of ONC’s proposal (particularly when

coupled with the information blocking exceptions that make sharing data the default setting) is that API Data Suppliers would bear the full cost of data exchange, even when such exchange does not benefit their organization or their patients. **CHA urges ONC to modify its policy to ensure that API Data Suppliers, which would include hospitals and health systems, are not facing significantly increased costs because API Users cannot be charged.** We also ask ONC to clarify whether API Data Suppliers would be allowed to recoup costs from API Users in light of the information blocking provisions.

- **Information Blocking**

Section 4004 of the 21<sup>st</sup> Century Cures Act amends the Public Health Service (PHS) Act by adding a new section 3022 that establishes a general rule prohibiting information blocking practices by certain actors, provides examples of those practices, permits exceptions to that rule and provides authority to impose penalties for violations of that rule. Significantly, it also contains a directive that health care providers are not to be punished for the failure of health information technology (IT) developers and vendors to meet their obligations with respect to their products. It also directs the Secretary to avoid duplication of penalties in establishing its policies for violations of the information-blocking rule.

#### *Definitions*

**CHA urges ONC to clarify the roles and responsibilities of proposed categories of Actors.**

For example, the proposed definitions of health information network and health information exchange are too broad and the distinction between them is unclear. CHA is concerned that, as ONC acknowledges in the preamble, the proposed definitions of health information network and of health information exchange could under certain circumstances include a health care provider. It is important to be clear about how these definitions apply because entities must understand the regulatory implications of defined practice and exceptions, and because they could face exposure to penalties.

The proposed definition of electronic health information (EHI) is overly broad and would lead to implementation challenges and unintended consequences. **ONC should limit the definition of EHI to the data classes established under the USCDI.**

ONC indicated that non-observational health information is considered EHI and includes data “created through aggregation, algorithms, and other techniques that transform observational health information into fundamentally new data or insights that are not obvious from the observational information alone.” CHA is concerned that this could create a disincentive for using and transforming health information for purposes of, for example, clinical decision support, quality measures, risk scores and examining population-level trends. Given the investment in technology and software necessary for those activities, the limitation on the ability to charge fees for access to the data created could have a chilling effect. **CHA urges ONC to clarify that non-observational data is not included in the definition of EHI.**

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- Price Information and Price Transparency

ONC also suggests in the preamble that price information could be considered EHI and seeks comment on whether treating price information as EHI could advance its desire to promote price transparency. While the goal of health care price transparency is laudable, CHA is concerned about leveraging the definition of EHI, and thus the access, exchange and use of electronic health information, to serve as a platform to inform consumers about potential pricing for services.

It is likely that including price information in the definition of EHI would exceed ONC's authority. The 21st Century Cures focused on improving the efficacy of health IT to assist in patient clinical care. Had Congress intended ONC to include price information as part of the information blocking provisions of Section 3022, it would have had to do so directly.

Including price information in the definition could cause harm to hospitals and other health care providers who consider it proprietary. Nor is it evident that any health IT product available to providers on the market can support such a broad array of functionalities as well as provide the clinical information to providers for appropriate and timely care delivery to their patients. An EHR is not the most efficient way to make this type of information available to the patient. Even if in the future an EHR could support this potentially enormous amount of information, the access of health care providers to the requisite clinical care information in an EHR should not be complicated by masses of information that do not bear on treatment decisions.

**CHA does not support adding price information to the definition of EHI and urges ONC to take other steps to address price transparency.** For example, ONC should work with CMS and stakeholders including hospitals and health systems, patient groups, insurers, medical societies and health policy experts to consider ways to approach price transparency. An important first step is defining the kind of information consumers would actually find useful in making decisions about their health care. Dumping too much of the wrong kind of price data, such as chargemasters, will merely confuse consumers, who are generally most interested in how much health services will cost them. To understand their out-of-pocket costs they need information about their health insurance coverage, and it makes more sense for them to get that from their insurers rather than health providers.

#### *Exceptions*

ONC proposes seven exceptions in order to identify reasonable and necessary activities and practices that do not constitute information blocking. While CHA appreciates and supports the inclusion of these exceptions, we do have several concerns.

Each exception is subject to numerous conditions. The burden of proof to demonstrate compliance with each exception is placed upon the Actor. CHA believes the proposed burden of proof is unreasonable and is likely to cause additional administrative, reporting and compliance burdens for providers. ONC has not made clear which type of documentation would be necessary

to demonstrate that an exception's requirements have been met at all times. While the proposed rule provides some general insight into practices that would implicate or violate the information blocking rule, **the final rule should include additional specific examples of practices and documentation that would satisfy each of the exceptions categories**, especially the exceptions for preventing patient harm, promoting the privacy or security of EHI and responding to infeasible requests from the perspective of health care providers.

#### *Potential Conflicts with HIPAA and 42 CFR Part 2*

CHA is concerned about how the proposed rule would interact with existing laws on the privacy and security of patient health information. While ONC believes its privacy exception does not conflict with HIPAA, we remain concerned that compliance with one set of rules could trigger a violation under the other law. For example, the proposed rule's focus on sharing the greatest amount of information possible conflicts with HIPAA's stress on providing the least amount of information necessary for the intended purpose. Pressure to comply with the proposed information-blocking rule could lead to a violation of the HIPAA privacy regulations. **CHA recommends that the agency take additional steps to align its proposal with the intent of the HIPAA law and regulations.** With respect to the exception for promoting the privacy and security of EHI, ONC should clarify that a practice that complies with any of the HIPAA Privacy Rule policies for required and permissive uses and disclosures of protected health information qualifies for the exception.

The proposed rule does not adequately address potential conflicts with the patient consent requirements of the 42 CFR. Part 2 substance abuse regulations. While ONC suggests the "preventing harm" exception could be invoked to withhold that data, it also said failure to release the rest of the record would be information blocking. We are concerned about this proposal since the current technology does not allow for segmentation of data in a patient's chart at such a level. **ONC should do more to resolve potential tensions between the proposed regulations and the requirements of 42 CFR Part 2.** CHA also continues to advocate for greater alignment between 42 CFR Part 2 and HIPAA. The current Part 2 requirements focus on patient privacy but run counter to the goals of interoperability and care coordination. Failure to integrate services and supports can lead to risks and dangers to individual patients, such as contraindicated prescription medicines and problems related to medication adherence.

#### *Effective Date*

ONC has proposed that the information blocking provisions would go into effect the day the rule is finalized. This would give hospitals and health systems no time to modify current practices or put new systems in place to implement the rule and ensure compliance, including generating the documentation required for the exceptions, and leave them vulnerable to penalties. **ONC should provide significant additional time, at least 18 months, for implementation of the information blocking provisions.**

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*Disincentives for Health Care Providers – Request for Information*

Section 3022(b)(2)(B) of the PHS Act provides that any health care provider determined by the OIG to have committed information blocking will be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable federal law, as the Secretary sets forth through notice and comment rulemaking. Providers currently face penalties for noncompliance in CMS programs. For example, participants must meet Promoting Interoperability program performance-based requirements and attest that they are not information blocking to receive their full payment. The existing penalties for noncompliance in the CMS programs are sufficient and CHA urges ONC not to adopt additional penalties.

CHA would also like to point out that many of the health care facilities and practitioners included in the proposed definition of health care provider did not benefit from the Medicare and Medicaid EHR Incentive Programs. Nonetheless, most of these providers (such as post-acute care facilities) have invested in health IT products to improve efficiency and quality of care furnished in their facilities. Their products may or may not be certified to ONC standards since CEHRT was developed for providers included in the Incentive Programs. ONC should consider the barriers these providers face in implementing EHR functions that support interoperability when assessing whether information blocking occurred. If CMS implements any disincentive or penalty structure, it should take this into account. It should also provide for an appropriate period of non-enforcement to permit all actors time to educate themselves and finalize organizational and individual policies to comply with the information-blocking rule.

Thank you for the opportunity to provide comments on the proposed Interoperability, Information Blocking, and the ONC Health IT Certification rule. If you should have any questions about these comments or would like additional information, please do not hesitate to contact Kathy Curran, Senior Director, Public Policy, at 202-296-3993.

Sincerely,



Lisa A. Smith  
Vice President  
Public Policy and Advocacy